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Petroleum HPV

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July 5, 2002

The Honorable Christie Whitman, Administrator  
U.S. Environmental Protection Agency  
P.O. Box 1473  
Merrifield, VA 22116

**Attention: Chemical Right to Know Program  
HPV Consortium  
Lubricating Oil Basestocks Test Plan**

Dear Administrator Whitman:

The American Petroleum Institute, on behalf of the Petroleum HPV Testing Group, is pleased to submit the Lubricating Oil Basestocks Test Plan and Robust Summary. Our consortium has chosen not to use the HPV Tracker system for submission of our test plans due to the complexity of petroleum substances categories and the associated test plans. We are therefore submitting this test plan, as well as the robust summary, directly to EPA to make available for public comment.

Electronic copies of the test plan (in .pdf format) and robust summary (in .pdf format and as an IUCLID export file) are accompanying this letter via email to the EPA HPV robust summary email address (<http://www.epa.gov/chemrtk/srbstsum.htm>). This submission is also being sent, via email, to the individuals listed below, including Mr. Charles Auer.

Please feel free to contact me (202-682-8344; [twerdokl@api.org](mailto:twerdokl@api.org)) or Tom Gray (202-682-8480; [grayt@api.org](mailto:grayt@api.org)) with any comments or questions you may have regarding this submission.

Sincerely,

Lorraine E. Twerdok  
Administrator, API Subscription Research Programs

cc: Charles Auer, EPA  
via email Rich Hefter, EPA  
Oscar Hernandez, EPA  
Petroleum HPV Testing Consortium Oversight and Technical Committees

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**HIGH PRODUCTION VOLUME (HPV) CHEMICAL CHALLENGE PROGRAM**

**TEST PLAN**

**LUBRICATING OIL BASESTOCKS CATEGORY**

**Submitted to the US EPA**

**by**

**The Petroleum HPV Testing Group**

**[www.petroleumhpv.org](http://www.petroleumhpv.org)**

**Consortium Registration #**

**March 24, 2003**

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## Plain Language Summary

This test plan addresses the petroleum refinery streams known as lubricating base oils, also referred to as base oils or lubricating basestocks. Base oils are the primary hydrocarbon components of industrial lubricants including engine oils, transmission fluids, hydraulic fluids, gear oils, metalworking oils, greases, heat transfer oils, general-purpose oils, and machine oils. The more intensively refined base oils (reduced levels of undesirable components) are used as food machinery lubricants, pharmaceutical white oils, laxatives, body lotions, cosmetics, direct food additives, and in a number of food-contact applications.

The materials in this category are complex petroleum mixtures composed primarily of saturated hydrocarbons with carbon numbers ranging from C15 to C50. At ambient temperatures lubricating base oils are liquids of varying viscosities, with negligible vapor pressures. Base oils are produced by first distilling crude oil at atmospheric pressure to remove lighter components (e.g. gasoline and distillate fuel components), leaving a residue (residuum) that contains base oil precursors. This atmospheric residuum is then distilled under vacuum to yield a range of distillate fractions (unrefined distillate base oils) and a vacuum residuum. Removal of the asphalt components of the vacuum residuum results in unrefined residual base oils. These distillate and residual base oil fractions may then undergo a series of extractive or transforming processes that improve the base oils' performance characteristics and reduce or eliminate undesirable components.

Given their process histories, compositional differences, and physicochemical differences, the streams within this HPV category can be divided into two subcategories:

- Distillate base oils, and
- Residual base oils.

The distillate base oils can be further grouped by degree of processing, levels of unwanted constituents, and expected mutagenicity and carcinogenicity potential:

- Unrefined & mildly refined distillate base oils, and
- Highly & severely refined distillate base oils.

Unrefined & mildly refined distillate base oils contain the highest levels of undesirable components, have the largest variation of hydrocarbon molecules and have shown the highest potential carcinogenic and mutagenic activities. Highly & severely refined distillate base oils are produced from unrefined & mildly refined oils by removing or transforming undesirable components. In comparison to unrefined & mildly refined base oils, the highly & severely refined distillate base oils have a smaller range of hydrocarbon molecules and have demonstrated very low mammalian toxicity. Mutagenicity and carcinogenicity testing of residual oils has been negative, supporting the Testing Group's belief that these materials lack biologically active components or the components are largely non-bioavailable due to their molecular size.

The Testing Group is proposing to perform a reproductive/developmental screening study (OECD 421) on a representative sample of a highly to severely refined distillate base oil (other than a food/drug grade white mineral oil). The limited reproductive and developmental data for highly & severely refined distillate base oils, coupled with positive effects for this endpoint in a study of heavy vacuum gas oil (a material similar to an unrefined distillate base oil) suggest the need for additional data on the highly & severely refined distillate oils.

The Testing Group is also proposing to perform a repeat-dose/reproductive/developmental screening study (OECD 422) on a representative sample of the residual base oils. The lack of adequate documentation of a complete data set on the repeat-dose endpoints, and the lack of reproductive and developmental toxicity endpoints for residual base oils suggest the need for a screening study on this subcategory of materials.

The Testing Group believes conducting these two studies will allow the Group to:

- Complete the SIDS (Screening Information Data Set) characterization of the mammalian toxicity of materials within the lubricating oil basestocks category, and
- Test the Group's hypotheses that:

- The reproductive and developmental toxicity of the distillate base oils is inversely related to the degree of processing, and
- The residual base oils lack repeat-dose, reproductive and developmental toxicity potential.

When physicochemical data did not exist or was impractical to obtain for the lubricating oil basestocks category, calculated physicochemical and environmental data for selected constituents of lubricating oil basestocks has been developed using the EPIWIN© computer model.

Substantial data was reviewed on the eco-toxicological characteristics of distillate and residual base oils. For fish, invertebrates and algae, no acute toxicity was measured in any of 20 tests. Furthermore, no chronic toxicity to aquatic invertebrates was found in 10 of 11 studies examined. The Testing Group thinks the existing ecotoxicity data on lubricating oil basestocks adequately describes their potential toxicity. Therefore the Testing Group is not proposing any additional ecotoxicity testing on any of the lubricating oil basestocks category members.

## Description of the Lubricating Oil Basestocks Category

The Lubricating Oil Basestocks category includes both refinery streams and finished products. The materials in this category are complex petroleum mixtures that boil between 700 and 1000°F (371-538°C) and are composed primarily of saturated hydrocarbons with carbon numbers ranging from C15 to C50. The molecular makeup of these oils consists of paraffinic, isoparaffinic, naphthenic, and aromatic hydrocarbon groupings that are varied in complexity and number. At ambient temperatures, all the materials in the category are liquids of varying viscosities with negligible vapor pressures and water solubility values. Because they are complex mixtures, the lubricating oil basestocks are typically not defined by detailed compositional information but instead by process history, physical properties, and product use specifications. Whereas detailed compositional information may be limited, general compositional information can be inferred from the base oil's physical properties – e.g. the higher the boiling temperature range of a fraction, the higher the molecular weight of the oil's components.

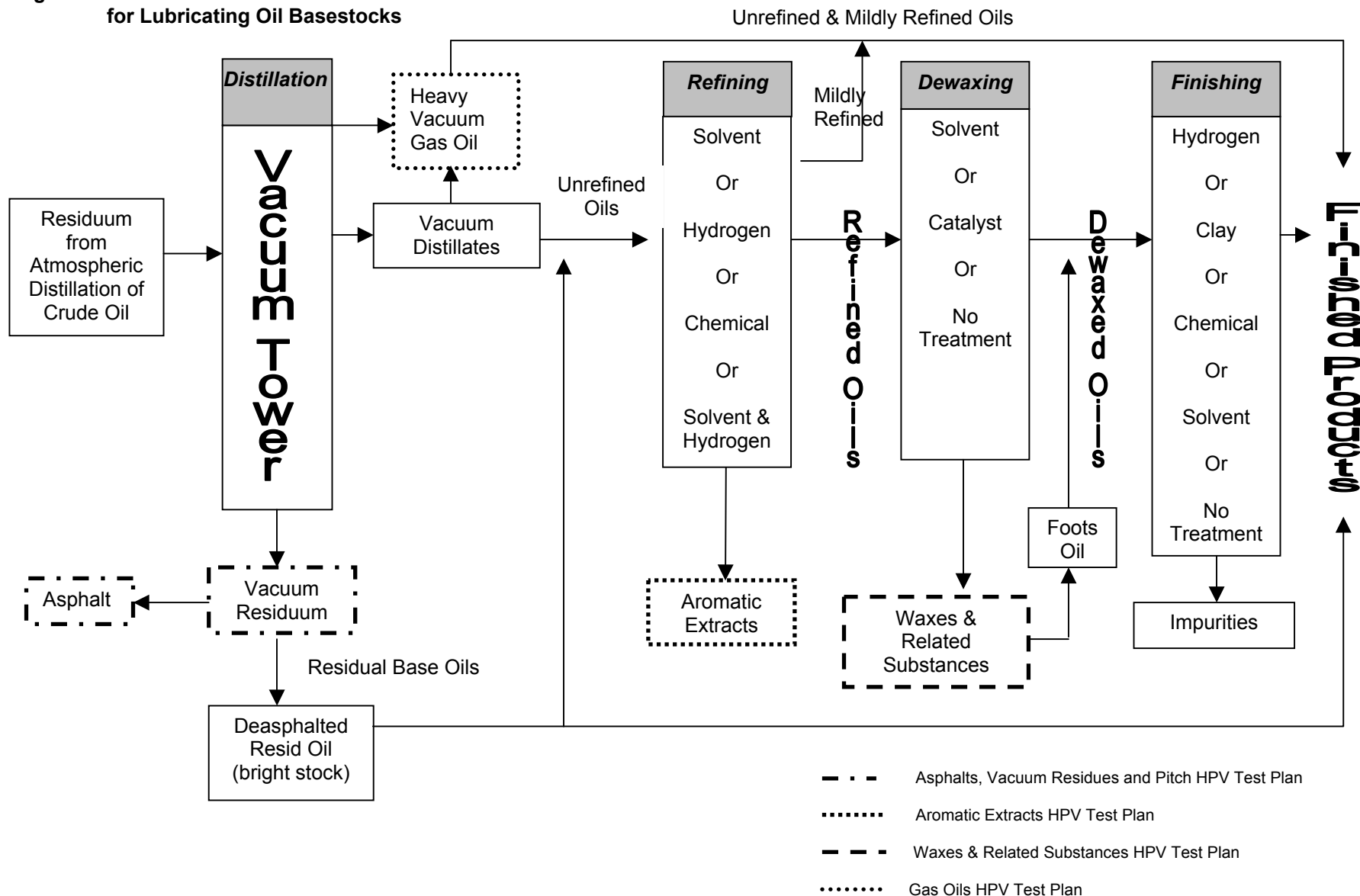
As shown in Figure 1, the materials included in the category are produced by the vacuum distillation of the residuum that results from the atmospheric distillation of crude oil. This vacuum distillation produces a range of distillate fractions (unrefined distillate base oils) and a vacuum residuum. As the boiling ranges of the fractions increase, the levels of polycyclic aromatic compounds (PACs), polycycloparaffins and heteratoms (N, O, S, and metals) increase, while the levels of paraffins decrease. This is shown schematically in Figure 2.

Removal of the asphalt components (e.g., asphaltenes, resins) of the vacuum residuum results in unrefined residual base oils. The unrefined distillate and residual base oils can either be blended into other process streams, or undergo additional refining in order to produce “finished” base oils. The additional refining consists of a series of extractive or transforming processes that improve the base oils' performance characteristics and remove, reduce or transform undesirable components. An example of the transformations that take place is that of hydrocracking, a process in which aromatics are converted to naphthenics and paraffins by catalytically breaking carbon-carbon bonds under high-pressure hydrogen.

The removed and transformed materials are deemed undesirable because they are either deleterious to product performance and/or are potentially carcinogenic. The undesirable components include aromatics, metals, waxes, and trace components causing unwanted colors or odors (i.e. sulfur). The aromatics include polycyclic aromatic compounds [PACs], some of which are heterocyclics, PACs with inclusions of N, S, O. Premium lube base stocks have low levels of nitrogen and sulfur, the hydrocarbons present being predominantly naphthenics and isoparaffins. Naphthenics have good low temperature viscosity and oxidative stability while isoparaffins possess excellent oxidation stability, good viscosity characteristics, and low volatility. Normal paraffins, however, have poor low temperature properties. Aromatics have high volatility and poor oxidative stability in most lubricant applications, and therefore, processing is directed toward reducing the aromatics content. Sulfur causes deposits, off color, and odor, while nitrogen causes deposits and promotes oxidation.

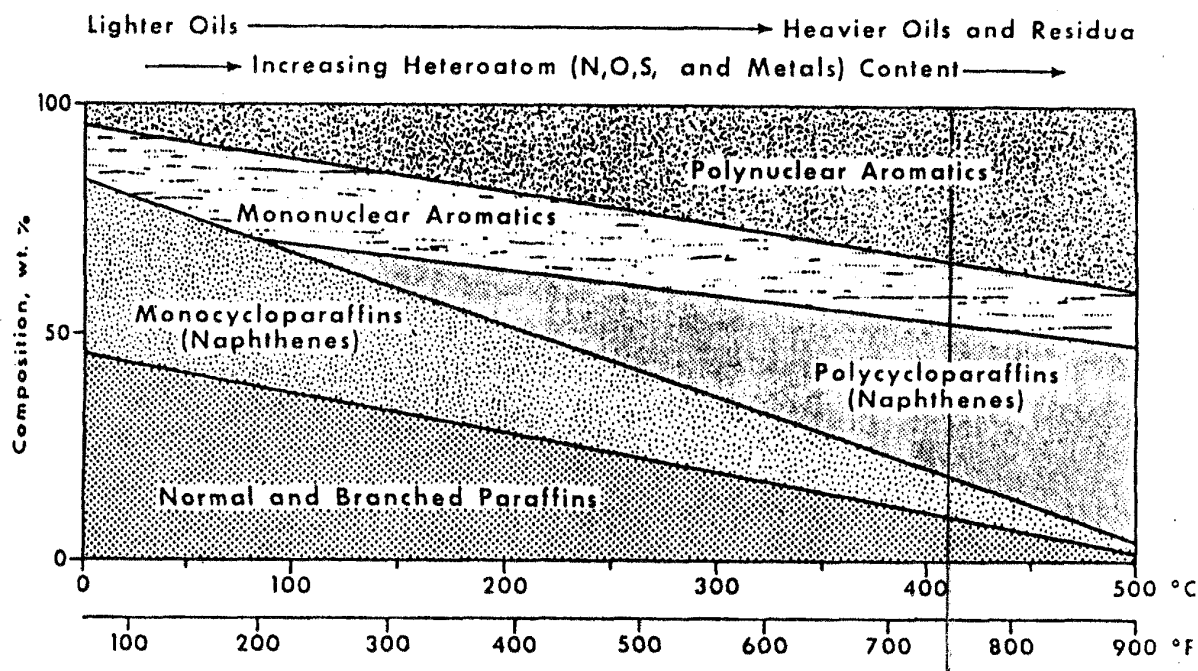
The more extensive the extractive and transforming processes an oil undergoes, the more “severe” is the oil's processing. Terms such as “mildly” and “highly” are also used to describe the degree of processing. Within the base oil category, the unrefined base oils contain the highest levels of undesirable components, have the largest variation of hydrocarbon molecules and in the case of distillate base oils, have shown the highest potential carcinogenic and mutagenic activity. Because of the “subtractive” nature of base oil processing, streams that have been “severely” or “highly” processed have much lower levels of undesirable components, a narrower range of hydrocarbon molecules and have demonstrated very low toxicity.

**Figure 1. Production Process Schematic  
for Lubricating Oil Basestocks**



Links to resources containing additional details regarding lubricating oil basestocks refining and petroleum processes in general can be found in Appendix B "Links to Additional Resources".

**Figure 2. Refinery Stream Composition – Boiling Range vs. General Composition**



Mobil, 1997

Based on the vacuum tower distillation fraction from which they originate and their corresponding physical-chemical properties, the thirty-six substances (see Appendix 1) included in the Lubricating Oil Basestocks Test Plan can be divided into two subcategories:

- Distillate base oils, and
- Residual base oils.

The distillate base oils can be further divided by degree of processing, levels of unwanted constituents, and expected mutagenicity and carcinogenicity potential into:

- Unrefined & mildly refined, and
- Highly & severely refined base oils.

Physical-chemical properties for selected base oils can be found in Table 1.

**Table 1. Physical-chemical Properties of Selected Lubricating Oil Basestocks**

Base oil description	Kinematic viscosity *		Flash Point (°C)	Pour Point (°C)	Density (kg/l)	Average Molecular Weight
	at 40°C (mm <sup>2</sup> /s)	at 100°C (mm <sup>2</sup> /s)				
<b>Distillate oils</b>						
Solvent-dewaxed, light paraffinic (64742-56-9)	8.4	2.4	157	-18	0.85	280
Solvent-dewaxed, heavy paraffinic (64742-65-0)	25.1	4.8	204	-12	0.86	390
Hydrotreated, light paraffinic (64742-55-8)	17.0	3.7	190	-18	0.86	360
Hydrotreated, heavy paraffinic (64742-54-7)	73.9	9.1	232	-9	0.88	500
Hydrotreated, light naphthenic (64742-53-6)	8.5	2.2	145	-60	0.87	290
Hydrotreated, heavy naphthenic (64742-52-5)	145	10.5	220	-24	0.91	440
White mineral oil (8042-47-5)	27.3	5.0	217	-15	0.86	400
<b>Residual oils</b>						
Solvent-dewaxed (64742-62-7)	1300	50	285	-6	0.95	700

\*Kinematic viscosity is often expressed in Centistokes (cSt), 1 mm<sup>2</sup>/second (mm<sup>2</sup>/s) = 1 cSt.

CONCAWE, 1997

### Distillate Base Oils

Distillate base oils contain components whose boiling points typically range from 300 to 600°C (CONCAWE, 1997). These materials are found in the majority of the lubricating products sold to the public. Distillate base oils are often described as either "naphthenic" (saturated ring hydrocarbons) or "paraffinic" (straight or branched chain hydrocarbons) depending on their crude source and/or the dominant hydrocarbons present. The difference between naphthenic and paraffinic base oils is one of relative percentage since, naphthenes and paraffins are present in both types of oils. Thus, a base oil might be called a paraffinic oil if it is 60% paraffins and 30% naphthenes or a naphthenic oil if it is 60% naphthenes and 30% paraffins. Base oils are also often described as either "light" (viscosity less than 19 cst @40°C) or "heavy" (viscosity greater than 19 cst@40°C). The naphthenic/paraffinic and light/heavy nomenclatures are primarily used to distinguish product application and lubricant quality parameters rather than health and safety characteristics, since a significant amount of toxicology data exists that shows little differentiation between these four classifications (see Appendix C, Robust Summary).

For the purposes of the HPV program, a more critical defining feature of the distillate base oils is the severity of the processing an oil has undergone. The focus on the degree of processing is supported by the physical-chemical characteristics of the materials, the subtractive nature of the processing the base oils undergo, and the existing toxicology database. Numerous tests have shown that a lubricating base oil's mutagenic and carcinogenic potential correlates with its 3-7 ring PAC content, and the level of DMSO

extractables, both characteristics that are inversely related to the degree/conditions of processing (Doak, et al., 1983; Halder, et al., 1984; IARC, 1984; Kane, et al., 1984; Singer, 1986; Chasey, et al., 1993; Roy, et al. 1988, 1996; Blackburn, et al., 1984; 1986; 1996; CONCAWE, 1994; EU, 1994). Based on the results published by Feuston, et al. (1994), the Testing Group thinks the same inverse relationship may exist for subchronic and other non-carcinogenic endpoints.

Using the extent of refining as a criterion, materials in the distillate base oils sub-category can be divided into two groups:

- Unrefined & mildly refined distillate base oils, and
- Highly & severely refined distillate base oils.

The unrefined & mildly refined distillate oils receive no or minimal treatment beyond the initial vacuum distillation. Consequently, they contain the highest levels of undesirable components, have the largest variation of hydrocarbon molecules and have shown the highest carcinogenic and mutagenic activity. Unrefined & mildly refined distillate oils are primarily used as feedstocks for the production of more highly refined base oils. They may also be used in a small number of applications such as certain general-purpose lubricants that are consumed in use (once-through lubricants) and heat treatment oils. Because human exposures to unrefined and mildly refined distillate base oils occur in occupational settings, human exposures are restricted to droplet aerosols, liquid on the skin and occasional accidental ingestion. However, these oils are all clearly labeled by the manufacturers as potential carcinogens and hazardous to health.

Refined distillate base oils are produced from unrefined base oil fractions by undergoing additional processing designed to reduce or transform the undesirable components (see Figure 1). In general, each additional step of processing (increasingly severe processing) results in:

- Lower levels of unwanted components; including aromatics, metals, waxes, and trace components causing unwanted colors or odors (i.e. sulfur), -
- A narrower range of hydrocarbon molecules (increasing concentration of paraffins and naphthenes), and
- Lower, if any, carcinogenic or mutagenic activity.

Some distillate base oils are destined for use in food, food contact, cosmetic, pharmaceutical and related applications. Known as white oils, these very severely refined distillate base oils undergo numerous processing steps that essentially eliminate or transform all undesired components, including unsaturated hydrocarbons and aromatics. When used in food, food contact, cosmetic, pharmaceutical and related applications, base oils have to meet stringent purity requirements as described in the respective national Pharmacopoeia and international legislations. These regulations generally specify melting ranges, color, polycyclic aromatic hydrocarbon content and other impurity limits (U.S. FDA, 2002; USP, 2002; CONCAWE, 1984, JECFA 2002).

Almost all commercial base oils used in the United States are highly refined. Others could be considered severely refined, yet are not medicinal, cosmetic or food grade white oils. Refined lubricants destined for commercial or industrial applications (non-medicinal/non-food/non-cosmetic) are not processed to the same level of severity as the white oils – thus leaving these highly refined base oils with very low, but measurable levels of sulfur and aromatics. These highly refined base oils display toxicological properties much closer to the food/drug/cosmetic grade white oils than they do to the unrefined & mildly refined base oils.

Detailed compositional and physical-chemical properties for two representative samples of materials that represent the boundaries of the distillate base oils sub-category are shown in Table 2.

**Table 2. Physical-chemical Properties of Representative Distillate Base Oil Samples**

	<b>Unrefined</b>	<b>Severely Refined</b> (medicinal grade)
<b>Avg Molecular Weight (gm/mol)</b>	300	320
<b>Density @15°C</b>	0.8651	0.857
<b>Viscosity @40°C (centistokes)</b>	14.07	13.3
<b>Viscosity @100°C (centistokes)</b>	2.79	3.08
<b>Pour Point (°F)</b>	+ 60	-32.8
<b>Distillation °F @ 760mm</b>		
<b>5% (vol)</b>	658	509
<b>50%</b>	711	689
<b>95%</b>	790	833
<b>Refractive Index RI units @20°C</b>	1.4815	1.4688
<b>Total Sulfur (wt %)</b>	0.38	<.0001
<b>Heavy Metals Total mg/kg</b>	<1	<1
<b>Hydrocarbon Type</b>		
<b>Nonaromatics (wt %)</b>	79.1	100
<b>Aromatics (wt %)</b>	20.9	<2x10 <sup>-5</sup>

API, 1987b  
CONCAWE, 1993

### Residual Base Oils

Residual base oils are derived from the residuum of the vacuum distillation tower and may contain components boiling as high as 800°C (CONCAWE, 1997). As can be seen from Table 1, the residual oils have molecular weights that are much higher than the distillate base oils. Residual base oils are primarily used in situations requiring oils with a high viscosity, e.g., gear oils.

As shown in Figure 2, residual oils have substantial PAC levels when assayed by traditional methods. On this basis, they would be expected to have mutagenic and/or carcinogenic activity. However, no adverse effects have been seen in either *in vitro* mutagenicity or dermal carcinogenicity testing of residual base oils, irrespective of the degree of processing they have undergone. Ultraviolet, HPLC/UV, GC/MS, and infrared analyses of these oils indicate that the aromatics they contain are predominantly 1-3 rings that are highly alkylated (paraffinic and naphthenic). Because they are found in such a high boiling material (> 1070°F), it is estimated that the alkyl side-chains of these 1-3 ring aromatics would be approximately 13 to 25 carbons in length. These highly alkylated aromatic ring materials are either devoid of the biological activity necessary to cause mutagenesis and carcinogenesis, or are largely non-bioavailable to the organisms (Roy, et al., 1988).

### Category Rationale and Test Material Description

The Testing Group made the following assumptions when analyzing the existing data, proposing testing and selecting test materials:

- The materials included in the Lubricating Base Oils category are related from both process and physical-chemical perspectives;
- The potential toxicity of a specific distillate base oil is inversely related to the severity or extent of processing the oil has undergone, since:

- The adverse effects of these materials are associated with undesirable components, and
- The levels of the undesirable components are inversely related to the degree of processing;
- Distillate base oils receiving the same degree or extent of processing will have similar toxicities;
- The potential toxicity of residual base oils is independent of the degree of processing the oil receives.

The Testing Group is proposing to perform a reproductive/developmental screening study (OECD 421) on a representative sample of a highly to severely refined distillate base oil (other than a food/drug grade white mineral oil). The limited reproductive and developmental data for highly & severely refined distillate base oils, coupled with positive effects for this endpoint in a study of heavy vacuum gas oil (a material similar to an unrefined distillate base oil) suggest the need for additional data on the highly & severely refined distillate oils.

The Testing Group is also proposing to perform a repeat-dose/reproductive/developmental screening study (OECD 422) on a representative sample of the residual base oils. The lack of a complete data set on the repeat-dose, reproductive and developmental toxicity endpoints for residual base oils suggest the need for a screening study on this subcategory of materials.

The Testing Group is not proposing any toxicity testing of unrefined & mildly refined oils. While no reproductive or developmental toxicity tests have been performed on these materials, the Testing Group believes the reproductive and developmental effects of these oils will be similar to those shown by heavy vacuum gas oil, a material similar to an unrefined distillate base oil. In comparison to the other members of the category, both heavy vacuum gas oil and the unrefined & mildly refined oils have higher levels of biologically active and available components.

The Testing Group believes conducting these two studies will allow the Group to:

- Complete its characterization of the mammalian toxicity endpoints in the Screening Information Data Set (SIDS) for the of materials within the lubricating oil basestocks category, and
- Test the Group's hypotheses that:
  - The distillate base oils reproductive and developmental toxicity potential is inversely related to the degree of processing, and
  - The residual base oils lack repeat-dose, reproductive and developmental toxicity potential.

Specific analytical data on the two base oil test samples will be available when the samples are obtained. The distillate oil test sample will have physicochemical and compositional properties similar to those shown in Table 2. For the residual oil test sample, the Testing Group will attempt to select an oil that has received a minimal amount of processing.

No additional mammalian or environmental fate/effects testing is proposed for the lubricant base oil category.

## **Evaluation of Existing Health Effects Data and Proposed Testing**

### **General Evaluation**

Many studies have been reported for this category of materials, ranging from acute to long-term carcinogenicity studies. Additional reviews by various individual authors and expert panels have also been published (Bingham et al., 1980; WHO, 1982; IARC, 1984; API, 1992; SCF, 1995; JECFA, 1996; CONCAWE, 1997). The toxicity testing has consistently shown that lubricating base oils have low acute toxicities. Numerous tests have shown that a lubricating base oil's mutagenic and carcinogenic potential correlates with its 3-7 ring PAC content, and the level of DMSO extractables (e.g. IP346 assay), both

characteristics that are directly related to the degree/conditions of processing (Halder, et al., 1984; IARC, 1984; Kane, et al., 1984; Chasey, et al., 1993; Roy, et al. 1988, 1996; Blackburn, et al., 1984, 1986; 1996; CONCAWE, 1994; EU 1994).

The Test Plan addresses the health effects endpoints of the category by:

- Evaluating the extensive toxicology database for the lubricating base oils,
- Using read-across information whenever possible among category members, and
- Proposing the minimal amount of mammalian toxicity testing needed to characterize the category and test the Testing Group's hypotheses:
  - The distillate base oils reproductive and developmental toxicity is inversely related to the degree of processing, and
  - The residual base oils lack reproductive and developmental toxicity potential.

## **Acute Toxicity**

### **Distillate Base Oils**

#### **Unrefined & Mildly Refined**

LD<sub>50</sub>s of >5000 mg/kg (bw) and >2g/kg (bw) for the oral and dermal routes of exposure, respectively, have been observed in rats dosed with an unrefined light paraffinic distillate (API, 1986d). The same material was also reported to be "moderately irritating" to the skin of rabbits (API, 1986d). When tested for eye irritation in rabbits, the material produced Draize scores of 3.0 and 4.0 (unwashed/washed eyes) at 24 hours, with the scores returning to zero by 48 hours (API, 1986d). The material was reported to be "not sensitizing" when tested in guinea pigs (API, 1986d).

#### **Highly & Severely Refined**

Multiple studies of the acute toxicity of highly & severely refined base oils have been reported. Irrespective of the crude source or the method or extent of processing, the oral LD<sub>50</sub>s have been observed to be >5 g/kg (bw) and the dermal LD<sub>50</sub>s have ranged from >2 to >5g/kg (bw) (API, 1986c; CONCAWE, 1997). The LC<sub>50</sub> for inhalation toxicity ranged from 2.18 mg/l to >4 mg/l (API, 1987a; CONCAWE, 1997). When tested for skin and eye irritation, the materials have been reported as "non-irritating" to "moderately irritating" (API, 1986c; CONCAWE, 1997). Testing in guinea pigs for sensitization has been negative (API, 1986c; CONCAWE, 1997).

### **Residual Base Oils**

There are no acute toxicity data available for the residual base oils. The Testing Group thinks the high molecular weight of these materials and associated low bioavailability preclude the systemic doses necessary to produce acute toxicity. Furthermore, tests of a variety of distillate base oils, including unrefined materials that contain high levels of biologically active materials, have consistently shown low acute toxicity.

**Summary: No additional testing is planned.** The Testing Group thinks the existing data is sufficient to characterize the acute toxicities of this category of materials. Multiple acute toxicity studies have been reported on a variety of distillate base oils. The studies have consistently found these materials to have low acute toxicities. The Testing Group believes there is no need for acute toxicity testing of residual oils given their low potential for human exposure, reported low bioavailability and lack of genotoxicity and dermal carcinogenicity.

## **Repeat-Dose Toxicity**

### **Distillate Base Oils**

#### **Unrefined & Mildly Refined**

Two hundred, 1000 and 2000 mg/kg (bw)/day of an unrefined base oil has been applied undiluted to the skin of male and female rabbits (API, 1986b). The test material was applied to the rabbits' skins 3 times/week for 4 weeks. To ensure maximum exposure, the applied material was covered with an occlusive dressing for 6 hours. In the high dose group, body weight gains were affected by treatment. These effects were largely due to effects on growth rate during the first week of the study. There were no significant differences between treated and control groups for any of the recorded hematological and clinical chemistry values. Gross and microscopic pathology findings relating to the treated skin were seen in all rabbits in the highest dose group. The findings consisted of "slight" to "moderate" proliferative changes in the treated skin.

#### **Highly & Severely Refined**

Two hundred, 1000 and 2000 mg/kg (bw)/day of a highly to severely refined base oil has been applied undiluted to the skin of male and female rabbits (API, 1986a). The test material was applied to the rabbits' skin 3 times/week for 4 weeks. To ensure maximum exposure, the applied material was covered with an occlusive dressing for 6 hours. Minimal to moderate skin irritation was observed in the various base oil dose groups. Throughout the study, male and female body weights in the high dose group and female body weights in the mid dose group were reduced when compared to their respective controls. Body weight gains observed in both male and female high dose groups were significantly lower than control values. At necropsy, the absolute testis weights and the relative weights of the right testis were lower in the high dose males than in controls. A common finding at necropsy in all the treatment groups was dry, scaly, rough, fissured, crusted and/or thickened skin. Histopathological examination revealed "slight" to "moderate" proliferative changes in the skin in all rabbits in the high dose group. These changes were accompanied by an increased granulopoiesis of the bone marrow. The testes of the majority of males in the high dose group had bilateral diffuse tubular hypoplasia accompanied by aspermatogenesis and atrophy of the accessory sex organs.

Repeat-dose dermal studies in rabbits have been reported for 15 different highly to severely refined base oils (all 28 day except one 21 day study) (CONCAWE, 1997). Doses have ranged from 200 to 5000 mg/kg/day, 3 times weekly. The primary effect in these studies was skin irritation, which ranged from "non" to "moderate". Systemic effects were observed in only one study. The effects consisted of a single incident of decreased body weight and increased relative liver weight, elevated SGOT and SGPT values and a sub-acute hepatitis.

Three highly to severely refined base oils have been tested in a four-week inhalation study (Dalbey, et al., 1991). Groups of male and female Sprague-Dawley rats were exposed to a base oil aerosol at nominal concentrations of 0, 50, 220 and 1000 mg/m<sup>3</sup>. Exposures were for 6 hours/day, 5 days/week. Apart from occasional diarrhea, there were no treatment related clinical observations and body weights were unaffected by exposure. No treatment related effects were found in any of the hematological or clinical chemical parameters that were measured. There was also no treatment related effect on sperm morphology. Wet and dry lung weights were increased in a dose related manner. For both males and females, the ratios of wet to dry lung weights were significantly increased at the highest dose concentrations of all three base oils. Treatment related changes were observed microscopically in the lungs and tracheobronchial lymph nodes of many of the treated animals. These changes consisted of the presence in the alveolar spaces of foamy macrophages with numerous vacuoles of varying size.

Subchronic oral toxicity studies have been carried out on six different food grade white oils (BIBRA, 1992). For ninety days, male and female Fischer 344 rats were fed diets containing severely refined base oils (white oils) at concentrations of 0.002, 0.02, 0.2 and 2.0% (w/w). The effects observed in the study were inversely related to the molecular weights of the six oils. The highest molecular weight material produced no effects other than increases (approximately 10%) in both food consumption and ASAT values in the males of the highest dose group. Histological examination revealed a small amount of mineral hydrocarbon in the livers of the male rats in the highest dose group. The lowest molecular weight base oil produced a similar increase in food consumption amongst males in the highest dose group. Treatment related increases in organ

weights (absolute and relative) and selected hematology and clinical chemistry values were also seen in both males and females. Histological examination of tissues from the high dose female group found a significant increase in hepatic granulomas and vacuolation of the lamina propria of the ileum and jejunum. In females, a treatment related histiocytosis was observed in the mesenteric lymph nodes beginning at the 0.02% dose level. Treatment related histiocytosis was also observed in the mesenteric lymph nodes of males, but was not observed below the 0.2% dose level. The study authors concluded that the LOEL values for five of the six base oils ranged from 0.002% to 0.02% dietary base oil concentrations. The NOEL for the oil with the highest molecular weight was a 2.0% dietary concentration.

In addition to the report summarized in the preceding paragraph, numerous repeat-dose oral toxicity studies on food-grade white oils have been reported in the open literature. Studies in Long Evans rats and Beagle dogs have reported no adverse effects (Bird, et al., 1990; McKee, et al., 1987b). Furthermore, studies with a low molecular weight white oil have demonstrated that the Fischer 344 rat is more sensitive in its response to mineral hydrocarbons than the Sprague Dawley rat (Firriolo et al., 1995).

The Testing Group believes the weight of evidence from all available data on highly & severely refined base oils support the Testing Group's presumption that a distillate base oil's toxicity is inversely related to the degree of processing it receives. The effects above do not contradict the Testing Group's hypothesis because:

- The granulomatous lesions induced by the oral administration of white oils are essentially foreign body responses. The lesions occur only in rats, of which the Fischer 344 strain is particularly sensitive,
- The testicular effects seen in rabbits after dermal administration of a highly to severely refined base oil were unique to a single study and may have been related to stress induced by skin irritation, and
- The accumulation of foamy macrophages in the alveolar spaces of rats exposed repeatedly via inhalation to high levels of highly to severely refined base oils is not unique to these oils, but would be seen after exposure to many water insoluble materials.

#### **Residual Base Oils**

No subchronic repeat-dose studies have been reported on residual base oils. However, two dermal carcinogenicity studies have been performed (see next section).

### **Carcinogenicity**

#### **Distillate Base Oils**

Although carcinogenicity is not an official endpoint of the HPV program, the Testing Group notes that numerous carcinogenicity studies have been carried out on lubricating base oil samples, ranging from "unrefined" to "highly refined". Data from these studies have been reported and reviewed elsewhere (Bingham, et al., 1980; Blackburn, et al., 1984, 1996; CONCAWE, 1994; 1997; IARC, 1984; Roy, et al., 1988, EMBSI, 2001b; Shoda, et al., 1997). The general conclusions that can be drawn from the animal carcinogenicity studies are:

- Highly & severely refined base oils are not carcinogens, when given either orally or dermally.
- Unrefined & mildly refined base oils are potential skin carcinogens.
- When applied repeatedly to the skin, carcinogenic base oils are associated only with skin tumors and not with an increase in systemic tumors.

#### **Residual Base Oils**

A dermal carcinogenicity study of a residual base oil in mice has been reported by King (1991). The test substance was described as "a non-solvent refined, deasphalted, dewaxed residual paraffinic lubricant base oil". For eighteen months, three times/week, undiluted test material was applied to the

skin of female CF1 mice. Two other groups of mice underwent similar treatments, but for only 22 or 52 weeks. The base oil produced minimal clinical evidence of skin irritation. No tumors of epidermal origin were observed in animals dosed with the base oil. Furthermore, no treatment-related effects were observed with regard to clinical condition, body weight gain, mortality or post mortem findings. Due to the lack of experimental detail in the published report, the Testing Group is unable to assign a Klimisch reliability score to the study. The data from this study provide important information on potential carcinogenicity and selected repeat-dose parameters. However, the existing study documentation does not provide data for a number of the endpoints contained in the SIDS repeat-dose study designs.

A second dermal carcinogenicity study of a residual base oil has been conducted in male C3H/HeJ mice (Exxon, 1984). The test substance was described as "deasphalted, dewaxed, residual oil". The test material was applied undiluted to the animals' backs, three times/week for 24 months. None of the animals treated with the test material developed skin tumors, or any other tumors considered treatment-related. Due to the lack of experimental detail in the published report, the Testing Group is unable to assign a Klimisch reliability score to the study. The data from this study provide important information on potential carcinogenicity and selected repeat-dose parameters. However, the existing study documentation does not provide data for a number of the endpoints contained in the SIDS repeat-dose study designs.

The absence of systemic toxicity in these two dermal carcinogenicity studies supports the Testing Group's belief that the high molecular weight of the residual base oils and the resulting low bio-availability preclude the internal doses necessary to elicit systemic toxicity.

**Summary: No additional testing is planned for distillate oils. The Testing Group proposes to test a representative sample of residual base oils by the dermal route of administration using a 28-day repeated-dose/reproductive/developmental toxicity screening protocol (OECD Test Guideline 422).** Multiple repeat-dose toxicity studies, utilizing a variety of exposure routes, have been reported on a variety of distillate base oils. The Testing Group believes the existing data is sufficient to characterize the repeat-dose toxicity of the distillate base oils. The Testing Group is proposing a repeat dose test (OECD Test Guideline 422) for residual base oils because the documentation of existing carcinogenicity studies does not provide data for a number of the endpoints contained in the SIDS repeat-dose study designs.

## **Genotoxicity**

### ***In-Vitro* (Mutagenicity)**

#### **Distillate Base Oils**

##### **Unrefined & Mildly Refined**

Modified Ames assays have been carried out on a number of base oils that were either unrefined or poorly refined. The oils were found to be mutagenic, with a strong correlation between mutagenicity and 3-7 ring PAC content (Blackburn, et al., 1986, Roy, et al., 1988).

##### **Highly & Severely Refined**

Several studies have reported the results of testing different base oils for mutagenicity using a modified Ames assay (Blackburn, et al., 1984, 1986; Roy, et al., 1988). Base oils with no or low concentrations of 3-7 ring PACs had low mutagenicity indices.

#### **Residual Base Oils**

Samples of a vacuum residuum and four residual base oils tested negative for the induction of frame shift mutations in modified Ames assays (EMBSI 2000, 2001a; Petrolabs, 1998; 2000). The Testing Group is unable to assign a Klimisch reliability score to these studies since they were obtained from a secondary source. However, the Testing Group believes the reported results are

consistent and the information is of sufficient quality and detail to allow it to be used to fulfill the data needs for the *in vitro* genotoxicity endpoint on the residual base oils subcategory.

### ***In-Vivo* (Chromosomal Aberrations)**

#### **Distillate base oils**

##### **Unrefined & Mildly Refined**

There are no *in vivo* genotoxicity data available for the unrefined base oils. *In vitro* assays (modified Ames) on a number of unrefined or poorly refined base oils have found a strong correlation between an oil's mutagenicity potential and its 3-7 ring PAC content (Blackburn, et al., 1986; Roy, et al., 1988).

The Testing Group expects the same correlation to exist for *in vivo* genotoxicity and expects unrefined & mildly refined base oils would be active in such studies. Consequently, the Testing Group is not proposing *in vivo* genotoxicity testing of unrefined & mildly refined base oils.

##### **Highly & Severely Refined**

A total of seven base stocks were tested in male and female Sprague-Dawley rats using a bone marrow cytogenetics assay (Conaway, et al., 1984). The test materials were administered via gavage at dose levels ranging from 500 to 5000 mg/kg (bw). Dosing occurred for either a single day or for five consecutive days. None of the base oils produced a significant increase in aberrant cells. The Testing Group is unable to assign a Klimisch reliability score to the study since it was obtained from a secondary source and does not contain raw data. However, the Testing Group believes the information is consistent with the results of *in vitro* mutagenicity tests on similar base oils and is of sufficient quality and detail to allow it to be used to fulfill the data needs for the *in vivo* genotoxicity endpoint on the "Highly & Severely refined" base oils.

#### **Residual Base Oils**

There is no *in vivo* genotoxicity data available for the residual base oils. However, *in vitro* mutagenicity tests have been conducted on residual base oils and have produced negative results. Dermal carcinogenicity studies on these materials have also been negative. Given these consistent results, and the low bioavailability of these materials, the Testing Group expects *in vivo* mutagenicity tests would also be negative. Consequently, the Testing Group is not proposing *in vivo* genotoxicity testing of a residual base oil.

**Summary: No additional testing is planned.** Existing *in vitro*, *in vivo* and carcinogenicity studies are adequate to characterize the genotoxicity of distillate and residual base oils.

### **Reproductive/Developmental Toxicity**

#### **Distillate Base Oils**

##### **Unrefined & Mildly Refined**

No reproductive or developmental toxicity studies have been reported for unrefined & mildly refined distillate base oils. However, a developmental toxicity screening study has been reported for heavy vacuum gas oil, a material with a process history similar to the unrefined distillate base oils (Mobil, 1987). As an unrefined vacuum distillate material, heavy vacuum gas oil contains the broadest spectrum of chemical components and highest concentration of bioavailable and/or biologically active components of all the materials addressed in this Test Plan. Because of their lack of or low level of processing, in comparison to other category members the unrefined lubricating base oils will also have higher concentrations of bioavailable and/or biologically active components.

In the Mobil study, heavy vacuum gas oil was applied daily to the skin of pregnant rats on days 0-19 of gestation. Dose levels administered included: 30, 125, 500 and 1000 mg/kg (bw)/day. All animals were euthanized on day 20. In the dams, the only dose-related finding at gross necropsy was pale colored lungs in four animals in the highest dose group and in one animal in the 500 mg/kg (bw)/day group. Mean thymus weights of the dams in the highest dose group were approximately half those of the control groups. Although absolute liver weights were unaffected by exposure to the gas oil, mean relative liver weights were increased (approximately 15%) in groups exposed to doses greater than 125 mg/kg (bw)/day. Maternal and fetal body weights were reduced at 500 and 1000 mg/kg (bw)/day. Significant increases in resorptions were also seen in these two dose groups. Soft tissue variations and malformations, and skeletal malformations were also increased at 500 and 1000 mg/kg (bw)/day.

### **Highly & Severely Refined**

In the three studies summarized below, highly or severely refined base oils were used as vehicle controls. Consequently, these studies provide limited evidence of the lack of developmental effects of highly & severely refined base oils. Although there were no untreated animals for comparison, the results were considered to be within normal limits.

A highly refined base oil was used as the vehicle control in a one-generation reproduction study (WIL, 1995). The study was conducted according to the OECD Test Guideline 421 "Reproductive/Developmental Toxicity Screening Test". A dose of 1.15 mg/kg (bw) of the base oil was administered daily by gavage to male and female Sprague Dawley rats. Rats were dosed for a minimum of 14 days prior to mating. Dosing was continued after mating until a total dosing period of 30 days had elapsed for males and until day 4 of lactation for females (39 days). There were no clinical findings. Growth rates and food consumption values were normal. There was no effect on fertility and mating indices in either males or females. At necropsy, there were no consistent findings and organ weights and histopathology were considered normal by the study's authors.

McKee, et al. (1987b) reported on a single generation study in which a white mineral oil (a food/drug grade severely refined base oil) was used as a vehicle control. Each of the two separate vehicle control groups contained male and female Sprague-Dawley rats. The dosed animals were given a single daily dose of 5 ml/kg (bw) of the base oil. Dosing was done via gavage, 5 days/week for 13 weeks. After 13 weeks of dosing, the animals were mated. The mated females were maintained without further dosing through gestation and lactation to post-partum day 21. Gross observations of pups and dams were generally unremarkable. In one base oil group, 3 malformed pups were found amongst 2 litters. Two of the malformed pups had syndactyly and renal agenesis, one of the pups also exhibited agnathia. The third pup had a small eye. In the other base oil group, four malformed pups were found amongst four litters. Two of the pups had tail abnormalities, one had a depression in the sternum and the fourth had a short snout. The study authors noted that a similar spectrum of malformations in Sprague-Dawley rats from the same supplier has been reported elsewhere. The authors also commented that this spectrum of malformations occurs spontaneously in the Sprague-Dawley rat.

A white mineral oil (food/drug grade severely refined base oil) was also used as a vehicle control in a developmental toxicity study in Sprague Dawley rats reported by McKee, et al., (1987a). Two separate groups of pregnant rats were administered 5 ml/kg (bw)/day of the base oil via gavage, on days 6 through 19 of gestation. In one of the two base oil dose groups, three malformed fetuses were found among three litters. One fetus had an extra lumbar vertebra, one had a discrete area of ossification in the area of the junction of the frontal and nasal bones, and the third had moderately dilated lateral ventricles of the brain. Three malformed fetuses were also found amongst three litters of the other base oil dose group. Two of these three fetuses had a vertebral arterial canal of a cervical process fully ossified, while the third fetus had angulated ribs. The study authors considered these malformations to be minor and within the normal ranges for the strain of rat.

### **Residual base oils**

There are no reproductive or developmental toxicity data available for the residual base oils.

**Summary: A representative sample of a highly to severely refined base oil (other than a food/drug grade white mineral oil) will be tested via the dermal route in a reproductive/developmental screening study (OECD 421). A representative sample of a residual base oil will be tested via the dermal route using a 28-day combined repeated-dose/reproductive/developmental toxicity screening protocol (OECD Test Guideline 422).** The limited reproductive and developmental data for highly & severely refined distillate base oils, coupled with positive effects for this endpoint in a study of heavy vacuum gas oil (a material similar to an unrefined distillate base oil) suggests the need for additional reproductive/developmental toxicity data on the highly & severely refined distillate oils. If the test of the highly to severely refined non-food/drug grade base oil is positive, the Testing Group will consider the need to perform a similar test on a food/drug grade white mineral oil. The lack of reproductive and developmental toxicity studies on residual base oils suggests the need for additional reproductive and developmental data on these materials. The Testing Group is not recommending testing of an unrefined to mildly refined lubricating base oil. The Testing Group believes the reproductive and developmental effects of the unrefined & mildly refined base oils are adequately addressed by data on heavy vacuum gas oil.

### **Evaluation of Existing Physicochemical and Environmental Fate Data**

#### **Physicochemical Data**

Although some data for products in this category exist, not all of these endpoints are defined and a consensus database for chemicals that represent products in this category does not exist. Therefore, calculated and measured representative data have been identified and a technical discussion provided, where appropriate. The EPIWIN<sup>®</sup> computer model, as discussed in the US EPA document entitled "The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program" has been used to calculate physical-chemical properties of representative constituents of lubricating base oils (U.S. EPA, 2000).

Because of the diversity of compounds encompassing lubricating base oils, it is not feasible to model the physicochemical endpoints for each potential compound. Rather, modeling efforts were directed towards those hydrocarbon components of the base oils that would most likely be dispersed to various environmental media. Since molecular weight and structural conformation determine in large part the solubility and vapor pressure characteristics of the hydrocarbons, modeling focused on representative lower molecular weight hydrocarbons (paraffinic, naphthenic and aromatic). The C15 hydrocarbons were selected since they are the shortest carbon chain length compounds in the base oils, which consist primarily of C15 to C50 compounds (CONCAWE, 1997).

#### **Melting Point**

For complex mixtures like petroleum products melting point may be characterized by a range of temperatures reflecting the melting points of the individual components. To better describe the physical phase or flow characteristics of petroleum products, the pour point is routinely used. The pour point is the lowest temperature at which movement of the test specimen is observed under prescribed conditions of the test (ASTM, 2002a). The pour point increases as an oil's viscosity increases. Pour point values for a variety of lubricating base oils have been reported in the literature (Doak, 1983; CONCAWE, 1984; 1993; 1997; Baker, 1984; Singh, et al. 1987; Sequeira, 1992; Montanari, et al., 1998). For example, the pour points measured for eight various unrefined and highly refined base oils ranged from -60 °C to -6 °C (CONCAWE, 1997).

**Summary: No additional testing is proposed.** The pour point of various lubricating base oils has been adequately measured.

#### **Boiling Point**

Because they are mixtures, lubricating base oils do not have a single numerical value for boiling point, but rather a boiling range that reflects the individual components. Constituent hydrocarbons of oils produced from vacuum distillation have boiling points ranging from about 300 to 800°C (CONCAWE, 1997). Boiling ranges for a variety of lubricating base oils have been reported (CONCAWE, 1984; McKee, et al., 1989; Skisak, et al., 1994; Kramer, 1999). For example, distillation ranges have been reported for three lubricating base oil refinery streams; 313 to 432 °C (unrefined, light paraffinic distillate: CAS No. 64741-50-0), 232 to 418 °C (hydrotreated light naphthenic; CAS No. 64742-53-6), and 338 to 604 °C (hydrotreated heavy naphthenic; CAS No. 64742-52-5) (API, 1987b).

**Summary: No additional testing is proposed.** The boiling range of lubricating base oils has been adequately addressed.

### Vapor Pressure

Vapor pressures of lubricating base oils are reported to be negligible (CONCAWE, 1997). In one study, the experimentally measured vapor pressure of a solvent-dewaxed heavy paraffinic distillate base oil was  $1.7 \times 10^{-4}$  Pa (Hazelton UK, 1991). For mixtures such as petroleum products, vapor pressure of the mixture is the sum of the partial pressures of the individual components (Dalton's Law of Partial Pressures). The vapor pressures of base oils cannot be measured experimentally due to analytical limitations for vapor pressure less than  $10^{-5}$  Pa. However, OECD Guideline 104, "Vapor Pressure" (1995), cites seven methods for determining vapor pressure (sensitivities ranging from  $10^{-5}$  to  $10^5$  Pa), including an estimation method. Therefore, the Testing Group estimated the vapor pressures for base oils with a modified Grain method using the EPIWIN computer software. Since base oils are mixtures of C15 to C50 paraffinic, naphthenic, and aromatic hydrocarbon isomers, representative components of those structures were selected to calculate a range of vapor pressures. The estimated vapor pressure values for these selected components of base oils ranged from  $4.5 \times 10^{-1}$  Pa to  $2 \times 10^{-13}$  Pa. Based on Dalton's Law the expected total vapor pressure for base oils would fall well below minimum levels ( $10^{-5}$  Pa) of recommended experimental procedures.

**Summary: No additional testing is proposed.** The vapor pressures of lubricating base oils are expected to be negligible and have been determined in one study to be  $1.7 \times 10^{-4}$  Pa.

### Partition Coefficient (Log $K_{ow}$ )

In mixtures such as the base oils, the percent distribution of the hydrocarbon groups (i.e., paraffins, naphthenes, and aromatics) and the carbon chain lengths determines in-part the partitioning characteristics of the mixture. Generally, hydrocarbon chains with fewer carbon atoms tend to have lower partition coefficients than those with higher carbon numbers (CONCAWE, 2001). However, due to their complex composition, unequivocal determination of the log  $K_{ow}$  of these hydrocarbon mixtures cannot be made. Rather, partition coefficients of selected C15 chain-length hydrocarbon structures representing paraffinic, naphthenic, and aromatic constituents in base oil lubricants were modeled using the EPIWIN<sup>®</sup>, WSKOW V1.40 computer model (U.S. EPA, 2000). Results showed typical log  $K_{ow}$  values from 4.9 and higher, which were consistent with values of >4 for lubricating oil basestocks reported by CONCAWE (CONCAWE, 1997).

**Summary: No additional modeling is proposed.** Partition coefficients ( $K_{ow}$ ) of 4.9 to 7.7 have been calculated for representative C15 hydrocarbon components of lubricating base oils.

### **Water Solubility**

When released to water, base oils will float and spread at a rate that is viscosity dependent. While water solubility of base oils is typically very low, individual hydrocarbons exhibit a wide range of solubility depending on molecular weight and degree of unsaturation (CONCAWE, 2001). Decreasing molecular weight (i.e., carbon number) and increasing levels of unsaturation increases the water solubility of these materials. As noted for partition coefficient, the water solubility of lubricating base oils cannot be determined due to their complex mixture characteristics. Therefore, the water solubility of individual C15 hydrocarbons representing the different groups making up base oils (i.e., linear and branched paraffins, naphthenes, and aromatics) was modeled using WSKOW V1.40. Based on water solubility modeling of those groups, aqueous solubilities are typically much less than 1 ppm.

**Summary: No additional modeling is proposed.** Water solubility values of 0.003 to 0.63 mg/L have been calculated for representative C15 hydrocarbon components of lubricating base oils.

### **Environmental Fate Data**

Because the materials included in this category are complex mixtures of differing compositions, it is not possible to measure or calculate a single numerical value for several of the environmental fate properties. Rather, these properties are defined by the range of individual hydrocarbon compounds in the lubricating base oils. The typical battery of tests used to measure the environmental fate of a material is not easily performed on the materials of this category because of their physical and chemical properties. Therefore, components of the lubricating base oils will be modeled where necessary using EPIWIN® (U.S. EPA, 2000).

### **Photodegradation**

Chemicals having potential to photolyze have UV/visible absorption maxima in the range of 290 to 800 nm. Some chemicals have absorption maxima significantly below 290 nm and consequently cannot undergo direct photolysis in sunlight (e.g. chemicals such as alkanes, alkenes, alkynes, saturated alcohols, and saturated acids). Most hydrocarbon constituents of the materials in this category are not expected to photolyze since they do not show absorbance within the 290-800 nm range. However, photodegradation of PAHs can occur and may be a significant degradation pathway for these constituents of lubricating base oils. The degree and rate at which PAHs may photodegrade depend upon whether conditions allow penetration of light with sufficient energy to effect a change. For example, PAC compounds bound to sediments may persist due to a lack of sufficient light penetration.

Atmospheric gas-phase reactions can occur between organic chemicals and reactive molecules such as photochemically produced hydroxyl radicals, ozone and nitrogen oxides. Atmospheric oxidation as a result of radical attack is not direct photochemical degradation, but indirect degradation. In general, lubricating base oils have low vapor pressures and volatilization is not expected to be a significant removal mechanism for the majority of the hydrocarbon components. However, some components (e.g., C15 branched paraffins and naphthenes) appear to have the potential to volatilize. In order to estimate the range of vapor-phase reactivity, calculation of atmospheric oxidation potential (AOP) was applied to specific C15 hydrocarbon components of lubricating base oils. The AOP was determined using the EPIWIN® model, AOPWIN V1.90 (U.S. EPA, 2000).

**Summary: No additional modeling is proposed.** Atmospheric half-lives of 0.10 to 0.66 days have been calculated for representative C15 hydrocarbon components of lubricating base oils.

### **Stability in Water**

Chemicals that have a potential to hydrolyze include alkyl halides, amides, carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters (Harris, 1982). Because lubricating base oils do not contain significant levels of these functional groups, materials in the lubricating base oils category are not subject to hydrolysis.

**Summary: Computer modeling will not be conducted for materials in the lubricating base oils category because they do not undergo hydrolysis.**

### **Chemical Transport and Distribution in the Environment (Fugacity Modeling)**

Fugacity-based multimedia modeling provides basic information on the relative distribution of chemicals between selected environmental compartments (e.g., air, water, soil, sediment, suspended sediment and biota). The US EPA has agreed that computer-modeling techniques are an appropriate approach to estimating chemical partitioning (fugacity is a calculated, not measured endpoint). A widely used fugacity model is the EQC (Equilibrium Criterion) model (Trent University, 1999). The EQC model is a Level 1 (i.e., steady state, equilibrium, closed system and no degradation) model that utilizes the input of basic chemical properties including molecular weight, vapor pressure, and water solubility to calculate distribution within a standardized regional environment. EPA cites the use of this model in its document "Determining the Adequacy of Existing Data" that was prepared as guidance for the HPV chemicals program (U.S. EPA, 1999).

Based on the physical-chemical characteristics of component hydrocarbons in lubricating base oils, the lower molecular weight components are expected to have the highest vapor pressures and water solubilities, and the lowest partition coefficients. These factors enhance the potential for widespread distribution in the environment. To gain an understanding of the potential transport and distribution of lubricating base oil components, the EQC model was used to characterize the environmental distribution of different C15 compounds representing different structures found in lube oils (e.g., paraffins, naphthenes, and aromatics). The modeling found partitioning to soil or air is the ultimate fate of these C15 compounds. Aromatic compounds partition principally to soil. Linear paraffins partition mostly to soil, while branching appears to allow greater distribution to air. Naphthenes distribute to both soil and air, with increasing proportions in soil for components with the greater number of ring structures. Because Level 1 fugacity modeling does not take into account degradation factors, levels modeled in the atmosphere are likely overstated in light of the tendency for indirect photodegradation to occur. Detailed results of this modeling, including a graphic representation, can be found in section 3.3.1 of the attached Robust Summary.

**Summary: No further modeling is proposed.** Fugacity-based computer modeling has been done for representative C15 hydrocarbon components of lubricating base oils.

### **Biodegradation**

Twenty-eight biodegradability studies have been reported for a variety of lubricating base oils. Based on the results of ultimate biodegradability tests using modified Sturm and manometric respirometry testing the base oils are expected to be, for the most part, inherently biodegradable. Biodegradation rates found using the modified Sturm procedure ranged from 1.5 to 29%. Results from the manometric respirometry tests on similar materials showed biodegradation rates from 31 to 50%. Biodegradation rates measured in 21-day CEC tests for similar materials ranged from 13 to 79% (BP International Ltd., 1990p-y; 1991a-k; Exxon Biomedical Sciences, Inc., 1995a-d; Shell Research Ltd., 1986; 1987).

The biodegradation rates given above are supported by the conclusions of a CONCAWE review of the biodegradation data for lubricating base oils (CONCAWE, 1997). The CONCAWE review concluded that the extent of biodegradation measured for a particular lubricating oil basestock is dependent not only on the procedure used but also on how the sample is presented in the biodegradation test. In spite of the presentation method, CONCAWE reported that lubricant base oils typically are not readily biodegradable in standard 28-day tests. However, since the oils consist primarily of hydrocarbons that are ultimately assimilated by microorganisms, CONCAWE considered the oils to be inherently biodegradable.

**Summary: No additional testing is proposed.** Sufficient data exists to characterize the biodegradability of the lubricating base oils.

### **EVALUATION OF EXISTING ECOTOXICITY DATA AND PROPOSED TESTING**

Numerous acute studies covering fish, invertebrates, and algae have been conducted to assess the ecotoxicity of various lubricating base oils. None of these studies have shown evidence of acute toxicity to aquatic organisms. Eight, 7-day exposure studies using rainbow trout failed to demonstrate toxicity

when tested up to the maximum concentration of 1000 mg/L applied as dispersions (BP International Ltd., 1990a-h). Three, 96-hour tests with rainbow trout (BP International Ltd., 1990i-k) also failed to show any toxic effects when tested up to 1000 mg/L applied as dispersions. Similarly, three 96-hour tests with fathead minnows at a maximum test concentration of 100 mg/L water accommodated fractions (WAF) (Exxon Biomedical Sciences Inc. 1995e-g) showed no adverse effects. Two species of aquatic invertebrates (*Daphnia magna* and *Gammarus* sp.) were exposed to WAF solutions up to 10,000 mg/L for 48 and 96-hours, respectively, with no adverse effects being observed (Shell Research Ltd., 1988). Four-day exposures of the freshwater green alga (*Scenedesmus subspicatus*) to 500 mg/L WAF solutions failed to show adverse effects on growth rate and algal cell densities in four studies (BP International Ltd., 1990l-o).

Multiple chronic ecotoxicity studies have shown no adverse effects to daphnid survival or reproduction. In 10 of 11 chronic studies, daphnids were exposed for 21 days to WAF preparations of lubricating base oils with no ill effects on survival or reproduction at the maximum concentration of 1000 mg/L (BP Oil Europe, 1995a-g; Shell Research Ltd., 1994, 1995). One test detected a reduction in reproduction at 1000 mg/L (Shell Research Ltd., 1995). Additional data provided in CONCAWE (1997) support findings of no chronic toxicity to aquatic invertebrates and fish. No observed effect levels ranged from 550 to 5,000 mg/L when tested as either dispersions or WAFs.

The data described above are supported by studies on a homologous series of alkanes reported by Adema (1986). The author concluded that the water solubility of carbon chains  $\geq C_{10}$  is too limited to elicit acute toxicity. This also was shown for alkylbenzene compounds having carbon numbers  $\geq C_{15}$ . Since base oils consist of carbon compounds of  $C_{15}$  to  $C_{50}$ , component hydrocarbons that are of acute toxicological concern are, for the most part, absent in these materials. Similarly, due to their low solubility, the alkylated two to three ring polyaromatic components in base oils are not expected to cause acute or chronic toxicity. This lack of toxicity is borne out in the results of the reported studies.

**Summary: No ecotoxicity testing is proposed.** Sufficient data exists to characterize the ecotoxicity of the lubricating base oils.

Data availability for the two subcategories of lubricating oil basestocks is summarized in the following table.

**Table 3. Matrix of Available Data and Proposed Testing**

	<b>DISTILLATE BASE OILS</b>		<b>RESIDUAL BASE OILS</b>
<b>TEST</b>	<b>UNREFINED &amp; MILDLY REFINED</b>	<b>HIGHLY &amp; SEVERELY REFINED</b>	
<b>Physical/Chemical Properties</b>			
Melting Point	Adequate	Adequate	Adequate
Boiling Point	Adequate	Adequate	Adequate
Vapor Pressure	Adequate	Adequate	Adequate
Water Solubility	Adequate	Adequate	Adequate
Partition coefficient (log Kow)	Adequate	Adequate	Adequate
<b>Ecotoxicity</b>			
Algae Growth Inhibition	Adequate	Adequate	Adequate
Acute Freshwater Invertebrate	Adequate	Adequate	Adequate
Acute Freshwater Fish	Adequate	Adequate	Adequate
Environmental Fate			
Biodegradation	Adequate	Adequate	Adequate
Stability in Water	N/A	N/A	N/A
Photodegradation (estimate)	Adequate	Adequate	Adequate
Transport and Distribution	Adequate	Adequate	Adequate
<b>Mammalian Toxicity</b>			
Acute	Adequate	Adequate	Adequate
Repeat-dose	Adequate	Adequate	Test
Reprod/Develop	Read Across <sup>1</sup>	Test	Test
Genotoxicity, <i>in vitro</i>	Adequate	Adequate	Adequate
Genotoxicity, <i>in-vivo</i>	Read Across <sup>2</sup>	Adequate	Read Across <sup>3</sup>

<sup>1</sup> Read Across from existing study on heavy vacuum gas oil.

<sup>2</sup> Read Across from *in vitro* and carcinogenicity data on unrefined & mildly refined base oils.

<sup>3</sup> Read Across from *in vitro* and carcinogenicity data on residual base oils.

Adequate: Indicates adequate existing data.

N/A: Indicates that evaluation of endpoint is Not Applicable due to physical-chemical properties

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## APPENDIX A.

### CAS Numbers and Definitions of Category Members

The CAS numbers and definitions of refinery streams, including lubricating oil basestocks, were developed in response to Section 8(b) of the Toxic Substances Control Act. This section of TSCA required identification and registration with the Environmental Protection Agency before July 1979 of each "chemical substance" being manufactured, processed, imported or distributed in commerce. Due to analytical limitations and known variability in refinery stream composition, identification of every specific individual molecular compound in every refinery process stream under all processing conditions was impossible. Recognizing these problems, the American Petroleum Institute (API) recommended to the EPA a list of generic names for refinery streams consistent with industry operations and covering all known processes used by refiners. The list, including generic names, CAS numbers and definition of each stream, was published by the EPA as "Addendum I, Generic Terms Covering Petroleum Refinery Process Streams."

Because of the variability inherent in the processing of petroleum materials, the definitions API developed for the CAS numbers are qualitative in nature, written in broad, general terms. The definitions often contain ranges of values, with little if any quantitative analytical information or concern for possible compositional overlaps. Many of the definitions also include information on the material's process history. In fact, process history and not chemical composition was one of the primary criteria used by API to differentiate streams and assign CAS numbers. In practice, process history was defined as the final process step a refinery stream had undergone. Information on intermediate processing steps was generally not included in the CAS definition. The result is that the CAS definitions for the lubricating oil basestocks often do not provide an accurate assessment of the refining history for a specific stream. For example, the CAS definition of a light paraffinic stream that has been solvent-refined, then clay treated and finally dewaxed will include only information on the final processing step, the dewaxing:

A complex combination of hydrocarbons obtained by removal of normal paraffins from a petroleum fraction by solvent crystallization. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100 °F (19 cSt at 40 °C).

In the list shown below, using the oils CAS definitions, the Testing Group has identified unrefined and residual base oils. Because of the lack of process history detail in the CAS definitions, the Testing Group is unable to assign a degree of refining to many of the remaining distillate base oils.

### DISTILLATE BASE OILS

#### Unrefined & Mildly Refined

##### CAS Number

64741-50-0

Distillates (petroleum), light paraffinic

A complex combination of hydrocarbons produced by vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated aliphatic hydrocarbons normally present in this distillation range of crude oil.

64741-51-1

Distillates (petroleum), heavy paraffinic

A complex combination of hydrocarbons produced by vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil with a viscosity of at least 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated aliphatic hydrocarbons.

64741-52-2

Distillates (petroleum), light naphthenic

A complex combination of hydrocarbons produced by vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64741-53-3

Distillates (petroleum), heavy naphthenic

A complex combination of hydrocarbons produced by vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil with a viscosity of at least 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

### **Highly & Severely Refined**

64741-76-0

Distillates (petroleum), heavy hydrocracked

A complex combination of hydrocarbons from the distillation of the products from a hydrocracking process. It consists predominantly of saturated hydrocarbons having carbon numbers in the range of C<sub>15</sub> through C<sub>39</sub> and boiling in the range of approximately 260°C to 600°C (500°F to 1112°F).

64741-88-4

Distillates (petroleum), solvent-refined heavy paraffinic

A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil with a viscosity of at least 100 SUS at 100°F (19cSt at 40°C).

64741-89-5

Distillates (petroleum), solvent-refined light paraffinic

A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C).

64741-96-4

Distillates (petroleum), solvent-refined heavy naphthenic

A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil with a viscosity of at least 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64741-97-5

Distillates (petroleum), solvent-refined light naphthenic

A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64742-18-3

Distillates (petroleum), acid-treated heavy naphthenic

A complex combination of hydrocarbons obtained as a raffinate from a sulfuric acid treating process. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil with a viscosity of at least 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64742-19-4

Distillates (petroleum), acid-treated light naphthenic

A complex combination of hydrocarbons obtained as a raffinate from a sulfuric acid treating process. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64742-34-3

Chemically Neutralized Heavy Naphthenic Distillate (petroleum)

A complex combination of hydrocarbons produced by a treating process to remove acidic materials. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil with a viscosity of at least 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64742-35-4

Chemically Neutralized Light Naphthenic Distillate (petroleum)

A complex combination of hydrocarbons produced by a treating process to remove acidic materials. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64742-37-6

Distillates (petroleum), clay-treated light paraffinic

A complex combination of hydrocarbons resulting from treatment of a petroleum fraction with natural or modified clay in either a contacting or percolation process to remove the trace amounts of polar compounds and impurities present. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated hydrocarbons.

64742-44-5

Distillates (petroleum), hydrotreated heavy naphthenic

A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having finished oil of at least 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64742-52-5

Distillates, (petroleum), hydrotreated heavy naphthenic

A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil of at least 100 SUS at 100 degree F (19cSt at 40°C). It contains relatively few normal paraffins.

64742-53-6

Distillates (petroleum), hydrotreated light naphthenic

A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64742-54-7

Distillates (petroleum), hydrotreated heavy paraffinic

A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil of at least 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated hydrocarbons.

64742-55-8

Distillates (petroleum), hydrotreated light paraffinic

A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated hydrocarbons.

64742-56-9

Distillates (petroleum), solvent-dewaxed light paraffinic

A complex combination of hydrocarbons obtained by removal of normal paraffins from a petroleum fraction by solvent crystallization. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C).

64742-63-8

Distillates (petroleum), solvent-dewaxed heavy naphthenic

A complex combination of hydrocarbon obtained by removal of normal paraffins from a petroleum fraction by solvent crystallization. It consists of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil of not less than 100 SUS at 100°F (19cSt at 40°C). It contains relatively few normal paraffins.

64742-65-0

Distillates (petroleum), solvent-dewaxed heavy paraffinic

A complex combination of hydrocarbons obtained by removal of normal paraffins from a petroleum fraction by solvent crystallization. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil with a viscosity not less than 100 SUS at 100°F (19cSt at 40°C).

64742-70-7

Paraffin oils (petroleum), catalytic dewaxed heavy

A complex combination of hydrocarbons obtained from a catalytic dewaxing process. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil with a viscosity of at least 100 SUS at 100°F (19cSt at 40°C).

64742-71-8

Paraffin oils (petroleum), catalytic dewaxed light

A complex combination of hydrocarbons obtained from a catalytic dewaxing process. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil with a viscosity of less than 100 SUS at 100°F (19cSt at 40°C).

72623-85-9

Lubricating oils (petroleum), C<sub>20-50</sub>, hydrotreated neutral oil-based, high-viscosity

A complex combination of hydrocarbons obtained by treating light vacuum gas oil, heavy vacuum gas oil, and solvent deasphalted residual oil with hydrogen in the presence of a catalyst in a two stage process with dewaxing being carried out between the two states. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil having a viscosity of approximately 112cSt at 40°C. It contains a relatively large proportion of saturated hydrocarbons.

72623-86-0

Lubricating oils (petroleum), C<sub>15-30</sub>, hydrotreated neutral oil-based

A complex combination of hydrocarbons obtained by treating light vacuum gas oil and heavy vacuum gas oil with hydrogen in the presence of a catalyst in a two stage process and dewaxing being carried out between the two stages. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>30</sub> and produces a finished oil having a viscosity of approximately 15cSt at 40°C. It contains a relatively large proportion of saturated hydrocarbons.

8042-47-5

White mineral oil (petroleum)

A highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulphuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps may be included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>50</sub>.

64742-58-1

Lubricating oils, petroleum, hydrotreated spent

A complex combination of hydrocarbons obtained by treating a spent lube oil with hydrogen in the presence of a catalyst. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C<sub>15</sub> through C<sub>50</sub>.

64742-67-2

Foots oil, petroleum

A complex combination of hydrocarbons obtained as the oil fraction from a solvent deoiling or a wax sweating process. It consists predominantly of branched chain hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub>.

Note from Testing Group \*\* Foots oil, obtained from the deoiling of wax made from vacuum distillate, is essentially an unrefined base oil, that undergoes similar process as any of the vacuum tower fractions – each step removing impurities and improving product performance.

72623-84-8

Lubricating oils, (petroleum) C15-30, hydrotreated neutral oil based solvent

### **Residual Base Oils**

64741-95-3

Residual oils (petroleum), solvent deasphalted

A complex combination of hydrocarbons obtained as the solvent soluble fraction from C<sub>3</sub> through C<sub>4</sub> solvent deasphalting of a residuum. It consists of hydrocarbons having carbon numbers predominantly higher than C<sub>25</sub> and boiling above approximately 400°C (725°F).

72623-83-7

Lubricating oils (petroleum) C<sub>25</sub>, hydrotreated bright stock-based

A complex combination of hydrocarbons obtained by treating solvent deasphalted residual oil with hydrogen in the presence of a catalyst in two stages with dewaxing carried out between stages. It consists predominantly of hydrocarbons having carbon numbers predominantly greater than C<sub>25</sub> and produces a finished oil with a viscosity of approximately 440cSt at 40°C. It contains a relatively large proportion of saturated hydrocarbons.

72623-87-1

Lubricating oils (petroleum), C<sub>20-50</sub>, hydrotreated neutral oil-based

A complex combination of hydrocarbons obtained by treating light vacuum gas oil, heavy vacuum gas oil and solvent deasphalted residual oil with hydrogen in the presence of a catalyst in a two stage process with dewaxing being carried out between the two stages. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C<sub>20</sub> through C<sub>50</sub> and produces a finished oil with a viscosity of approximately 32cSt at 40°C. It contains a relatively large proportion of saturated hydrocarbons.

64742-01-4

Residual oils (petroleum), solvent-refined

A complex combination of hydrocarbons obtained as the solvent insoluble fraction from solvent refining of a residuum using a polar organic solvent such as phenol or furfural. It consists of hydrocarbons having carbon numbers predominantly higher than C<sub>25</sub> and boiling above approximately 400°C (725°F).

64742-57-0

Residual oils (petroleum), hydrotreated

A complex combination of hydrocarbons obtained by removal of long, branched chain hydrocarbons from a residual oil by solvent crystallization. It consists of hydrocarbons having carbon numbers predominantly greater than C<sub>25</sub> and boiling above approximately 400°C (752°F).

64742-62-7

Residual oils, petroleum, solvent-dewaxed

A complex combination of hydrocarbons obtained by removal of long, branched chain hydrocarbons from a residual oil by solvent crystallization. It consists of hydrocarbons having carbon numbers predominantly greater than C<sub>25</sub> and boiling above approximately 400 degree C (752°F).

## **Appendix B.**

### **Links to Additional Resources**

#### **Refining Processes: General Descriptions**

[http://www.chevron.com/about/learning\\_center/refinery](http://www.chevron.com/about/learning_center/refinery)  
<http://www.lubrizol.com/lubetheory/default.htm>  
<http://www.orionrefining.com/flow.htm>  
[http://www.osha-slc.gov/dts/osta/otm/otm\\_toc.html](http://www.osha-slc.gov/dts/osta/otm/otm_toc.html)  
[http://www.shellglobalsolutions.com/base\\_oils/library/library.htm](http://www.shellglobalsolutions.com/base_oils/library/library.htm)  
<http://www.shell-lubricants.com/learningcenter/aboutoil.html>  
[http://www.shellus.com/welcome/history/hist\\_oil\\_main.html](http://www.shellus.com/welcome/history/hist_oil_main.html)  
<http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/petrefsnpt1.pdf>  
[http://www.mts.net/~dbrad1/base\\_oil.htm](http://www.mts.net/~dbrad1/base_oil.htm)

#### **Petroleum Related Glossaries**

[http://www.caltex.com.au/products\\_glo.asp](http://www.caltex.com.au/products_glo.asp)  
<http://www.citgo.com/CommunityInvolvement/Classroom/Glossary.jsp>  
<http://www.epplp.com/gloss.html>  
[http://www.prod.exxon.com/exxon\\_productdata/lube\\_encyclopedia/](http://www.prod.exxon.com/exxon_productdata/lube_encyclopedia/)  
[http://www.hellenic-petroleum.gr/english/glossary/gl\\_main.htm](http://www.hellenic-petroleum.gr/english/glossary/gl_main.htm)  
[http://www.prod.exxon.com/exxon\\_productdata/lube\\_encyclopedia/](http://www.prod.exxon.com/exxon_productdata/lube_encyclopedia/)  
<http://www.oilanalysis.com/dictionary>  
<http://www.orionrefining.com/glossary.htm>  
<http://www.gedolbear.com/glossary.htm>  
[http://www.shellglobalsolutions.com/base\\_oils/glossary/a\\_g.htm](http://www.shellglobalsolutions.com/base_oils/glossary/a_g.htm)  
[http://www.ursa-texaco.com/English/glossary\\_a.html](http://www.ursa-texaco.com/English/glossary_a.html)  
[http://www.eia.doe.gov/pub/oil\\_gas/petroleum/data\\_publications/petroleum\\_marketing\\_annual/current/pdf/glossary.pdf](http://www.eia.doe.gov/pub/oil_gas/petroleum/data_publications/petroleum_marketing_annual/current/pdf/glossary.pdf)

**Appendix C.**  
**Robust Summary**  
**(Separate document)**

**ROBUST SUMMARY  
OF INFORMATION ON**

**Substance Group**

# **LUBRICATING OIL BASESTOCKS**

**Summary prepared by**

American Petroleum Institute

**Creation date:** July 24, 2001

**Printing date:** March 24, 2003

**Date of last Update:** **March 24, 2003**

**Number of pages:** **85**

NB. Reliability of data included in this summary has been assessed using the approach described by Klimisch et al.

Klimisch, H. J., Andreae, M. and Tillman, U, (1997)

A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data.  
Regulatory Toxicology and Pharmacology 25, 1-5.

# 1. General Information

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

## 1.1.1 GENERAL SUBSTANCE INFORMATION

**Substance type** : Petroleum product  
**Physical status** : Liquid

**Remark** : The group of base oils consists of products that are derived from both distillates and residues of the vacuum distillation process in petroleum refining.

Base oils consist predominantly of hydrocarbons but may also contain small quantities of sulfur and nitrogen compounds with traces of a number of metals. The oils contain complex hydrocarbons with variable mixtures of paraffins, naphthenes and aromatics with carbon numbers in the range 15 to 50. Hydrocarbon constituents derived from vacuum distillates boil generally in the range 300 to 600 °C, whereas those derived from residual oils may boil up to 800 °C.

Unrefined vacuum distillates contain polycyclic aromatic compounds (PACs) which are removed during any subsequent refining process. The more severe the refining, the lower the PAC content will be of the refined base oil.

Physical chemical data for a range of base oils have been summarized by CONCAWE and these are tabulated in the attached document.

For most of the mammalian toxicology endpoints, information has been used that was derived by the American Petroleum Institute on a wide range of base oils. For simplicity, this robust summary contains detailed information on an API sample of an unrefined distillate (high PAC) and an API sample of a highly refined distillate (low PAC). If data was available on other samples, it has either been summarized in tabular form in the relevant sections of this summary or discussed in detail when appropriate.

The API sample of highly refined base oil for which data have been selected is one with a low average molecular weight since this is likely to represent the worst case from a toxicological perspective.

The physico-chemical characteristics of the two samples are as follows:

	Method	Unrefined oil	Highly refined oil
API sample No.		84-01	83-12
CAS No.		64741-50-0	64742-53-6
API Gravity @60°	D287	31.9	25.9
Density @15°C	D287	0.8651	0.8981
Molecular wt. (gm/mol)	D2224	300	260

## 1. General Information

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

Refractive index (RI units @20 °C)		1.4815	1.4910
Total Sulfur (wt. %)	D3120	0.38	0.04
Total Nitrogen (ppm/wt)	Chemil	210	38
Total oxygen (wt.%)	NAA	0.038	0.077
Total Chloride (ppm/wt)	coulom	11	2
Viscosity (cSt @ 40°C)	D445	14.07	0.44
Viscosity (cSt @ 100°C)	D445	2.79	2.14
Pour point (°F)	D93	+60	<-20
Carbon residue (wt. %)	D524	0.15	0.14
Distillation	D1160		
	IBP (°F)	595	450
	FBP (°F)	810	785
Hydrocarbon type analysis			
Nonaromatics (wt. %)	D2549	79.1	67.3
Aromatics (wt. %)	D2549	20.9	31.9
	TOTAL	100	100

Some oils are destined for food use or pharmaceutical applications and for these the refining process that they undergo is particularly severe to ensure that aromatic materials have been removed and that the resulting oil is colorless. Such oils are known as white oils. Unlike the other base oils in which oral intake is unintentional, the white oils are intended for uses in which an oral intake is likely. For these materials, oral studies are available and, where appropriate, are included in this Robust Summary.

Several individual companies have generated data on environmental effects and ecotoxicity. The relevant CAS descriptions of the materials that have been tested are included in the relevant sections of this robust summary.

**Attached document** : See Attachment 1. Physico-chemical Properties for Selected Lubricating Oil Basestocks

(71)

### 1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

**Type of limit** : TLV (US)  
**Limit value** : 5 mg/m<sup>3</sup>  
**Short term exposure limit value**  
**Limit value** : 10 mg/m<sup>3</sup>

**Remark** : A TWA TLV of 0.005 mg/m<sup>3</sup> is proposed for the sum total of 15 polynuclear aromatic hydrocarbons (PAHs) listed as carcinogens by the U.S. National Toxicology Program (NTP).

(1)

## 1. General Information

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

### 1.13 REVIEWS

**Memo** : IARC reviewed, in 1984, the carcinogenicity information on lubricating base oils and the outcome of their review was published in a Monograph.

(89)

**Memo** : Bingham reviewed the literature for information on the carcinogenic potential of petroleum hydrocarbons. This review contained information on base oils.

(21)

**Memo** : CONCAWE demonstrated that it was possible to distinguish between carcinogenic and non-carcinogenic base oils on the basis of the level of DMSO extractables. This approach was subsequently adopted in the EU for classification purposes.

**Remark** : The DMSO method was adopted subsequently in the EU to distinguish between carcinogenic and non-carcinogenic oils for classification and labeling purposes.

(70) (75)

**Memo** : The EU Scientific Committee for Food (SCF) and the WHO Joint Expert Committee on Food Additives (JECFA) have reviewed the available data on the toxicology of mineral hydrocarbons for food uses.

(90) (99)

**Memo** : The WHO published an Environmental Health Criteria document which included summarized information on lubricating base oil stocks

(112)

## 2. Physico-Chemical Data

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

### 2.1 MELTING POINT

**Method** : ASTM D97  
**GLP** : No data  
**Test substance** : Lubricating Base Oils; distillate oils, residual oils, and white oils various

**Remark** : By definition, melting point is the temperature at which a solid becomes a liquid at normal atmospheric pressure. For complex mixtures like petroleum products, melting point may be characterized by a range of temperatures reflecting the melting points of the individual components. To better describe phase or flow characteristics of petroleum products, the pour point is routinely used. The pour point is the lowest temperature at which movement of the test specimen is observed under prescribed conditions of the test (ASTM 2002). In addition, the pour point methodology defines a "no-flow" point, defined as the temperature of the test specimen at which a wax crystal structure or viscosity increase, or both, impedes movement of the surface of the test specimen under the conditions of the test (ASTM 2002). Because not all petroleum products contain wax in their composition, the pour point determination encompasses either change in physical state (i.e., crystal formation) and/or viscosity property.

**Result** :

<u>Oil type</u>	<u>Pour Point, °C</u>
<b>Distillate oils</b>	
Solvent de-waxed, light paraffinic (CAS No. 64742-56-9)	-18
Solvent de-waxed, heavy paraffinic (CAS No. 64742-65-0)	-12
Hydrotreated, light paraffinic (CAS No. 64742-55-8)	-18
Hydrotreated, heavy paraffinic (CAS No. 64742-54-7)	-9
Hydrotreated, light naphthenic (CAS No. 64742-53-6)	-60
Hydrotreated, heavy naphthenic (CAS No. 64742-52-5)	-24
White mineral oil (CAS No. 8042-47-5)	-15
<b>Residual Oils</b>	
Solvent de-waxed (CAS No. 64742-62-7)	-6

## 2. Physico-Chemical Data

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

**Reliability** : (2) Valid with restrictions  
Results of standard method testing were reported in a reliable review dossier.  
(16) (17) (71)

### 2.2 BOILING POINT

**Method** : Calculated by: MPBPWIN V1.40 (EPIWIN V3.10; US EPA 2000)  
**GLP** : No  
**Test substance** : American Society for Testing and Materials (ASTM). 2002. Standard Test Method for Pour Point of Petroleum Products (Rotational Method). ASTM D5985-02, Volume 05.01, ASTM, West Conshohocken, PA.

**Remark** : The substances covered in lubricating base oils are complex and variable mixtures of paraffins, naphthenes (cycloparaffins), and aromatics having carbon numbers ranging from about 15 to 50. Because they are mixtures, lubricating base oils do not have a single numerical value for boiling point, but rather a boiling range that reflects the individual components. Base oils are produced from vacuum distillation of the residue obtained after the atmospheric distillation of crude oil. The vacuum distillates and the vacuum residues together form the general group of unrefined or mildly refined base oil. Additional treatments or refinements such as solvent extraction, dewaxing, and hydrogenation, are employed to produce oils with desirable properties. The ranges of components modeled using MPBPWIN V1.40 are given in the table above. Those values are consistent with information provided by CONCAWE (1997) that indicated component hydrocarbons of oils produced from vacuum distillation have boiling points ranging from 300 to 600°C whereas those produced from vacuum residues contain components with boiling points as high as 800°C (CONCAWE 1997).

**Result** : See Remarks Section  
Calculated Boiling Point Ranges, °C:  
C15 to C50 Paraffinic: 250 to 682  
C15 to C50 Naphthenic: 282 to 683  
C15 TO C50 Aromatic: 312 to 788

**Reliability** : (2) Valid with restrictions  
(71) (110)

### 2.4 VAPOUR PRESSURE

**Method** : Directive 84/449/EEC, A.4 "Vapour pressure"  
**Year** : 1991  
**GLP** : Yes  
**Test substance** : CAS No. 64742-65-0, Distillates (petroleum), solvent-dewaxed heavy paraffinic

**Result** : Three runs on the sample were conducted. There was initially substantial reduction (equivalent to 3°C temperature change) of estimated VP on prolonged pumping after Run 1 but this was reduced to the equivalent of 0.65°C change between Runs

## 2. Physico-Chemical Data

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

- 2 and 3. The latter runs provided values at room temperature of  $1.882$  and  $1.563 \times 10^{-4}$  Pascals, yielding a mean value of  $V_p(298.15K) = 1.723 \times 10^{-4}$  Pascals. The condensation rates onto the pan observed in Run 3 increased with temperature more rapidly than the mass difference indicating an increasing efficiency of condensation and thus precluding the use of the condensation data to produce a satisfactory VP relation. The final values of rate of condensation were however equivalent in pressure regime to the mass differences assuming a rough equality between the numerical magnitudes of temperature and molar mass.
- Test condition** : The vapor pressure (VP) was determined using a VP balance based on a CI Electronics micro-balance with a sensitivity of approximately  $0.1$  mg. Sample temperature was controlled electronically ( $\pm 1^\circ\text{C}$ ) over the range from ambient to  $250^\circ\text{C}$ . Mass readings and temperature were recorded directly onto a 2-channel chart recorder. The VP balance was designed such that on opening the slide across the orifice in the temperature controlled evaporation furnace, the escaping vapor jet was directed at the scale pan. VP was determined directly from the pressure on the scale pan by measuring the difference of mass readings when the slide across the orifice was open and closed. When condensation occurred onto the pan the VP can be calculated from the condensation rate if the molar mass is known. VP of the sample was measured at several temperatures to yield VP curves for subsequent extrapolation to give  $298.15K$  values. Slope and intercept of VP curve were estimated by an unweighted least squares statistical treatment of the data and errors are  $\pm$  standard deviation of the respective quantity. Maximum and minimum values of VP at  $298.15K$  were calculated directly from the VP relationship using the ranges of errors in slope and intercept respectively. The quoted errors in VP at  $298.15K$  were then calculated directly by extrapolation from these values.
- Reliability** : (1) Valid without restriction

(88)

### 3. Environmental Fate and Pathways

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

#### 3.1.1 PHOTODEGRADATION

<b>Method</b>	: Calculations by EPIWIN V3.10; AOPWIN V1.90.
<b>Year</b>	: 2001
<b>GLP</b>	: No
<b>Test substance</b>	: CAS No.: Various; Unrefined and acid treated base oils.
<b>Remark</b>	: AOPWIN V1.90 calculates atmospheric oxidation half lives of hydrocarbons in contact with hydroxyl radicals in the troposphere, under the influence of sunlight. Atmospheric oxidation rates were calculated for the lowest molecular weight constituents, i.e., C15 hydrocarbon components. Although the low vapor pressures of these base oils indicate that volatilization will not be a very significant fate process, oxidation half-lives indicate this may be a moderate removal process if these substances were introduced to the atmosphere by adsorption to particulate matter via atmospheric emissions. The half-lives for degradation of these hydrocarbons by reaction with hydroxyl radicals, in the troposphere, under the influence of sunlight, will all be less than one day, by extrapolation from the data quoted by Atkinson (1990).  In general, most products in the base oil category do not contain component molecules that will undergo direct photolysis. Saturated hydrocarbons (paraffins and naphthenics), and single ring aromatics, which constitute the majority of these components, do not absorb appreciable light energy above 290 nm. Therefore, direct photolysis will not contribute to a measurable degradative removal of chemical components in this category from the environment.
<b>Result</b>	: Indirect photolysis at 25 °C Concentration of sensitizer: $1.50 \times 10^6$ OH radicals/cm <sup>3</sup> Rate constant: $18.1757 \times 10^{-12}$ cm <sup>3</sup> /mol-sec Half-life: 0.053 - 0.66 days for C15 hydrocarbon constituents
<b>Reliability</b>	: (2) Valid with restrictions The predicted endpoint was determined using a validated computer model.

(19) (72) (109)

#### 3.1.2 STABILITY IN WATER

<b>GLP</b>	: No
<b>Result</b>	: Measured value: N/A Degradation %: N/A Half-life: N/A Breakdown products: N/A
<b>Conclusion</b>	: Hydrolysis of an organic chemical is the transformation process in which a water molecule or hydroxide ion reacts to form a new carbon-oxygen bond. Chemicals that have a potential to hydrolyze include alkylhalides, amides,

### 3. Environmental Fate and Pathways

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters. The chemical components that comprise the base oil category are hydrocarbons, which are not included in these chemical groups, and they are not subject to hydrolysis reactions with water.

**Reliability** : (1) Valid without restriction

(87)

#### 3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

**Type** : Mathematical computer model  
**Media** : Soil, air, water, suspended sediment and sediment for C15 hydrocarbon structures  
**Method** : Calculations by EQC V2.11  
**Year** : 1999

**Remark** : Model based on chemical fugacity. Multimedia distribution was calculated for C15 hydrocarbons, the lowest molecular components found in base oils. Larger molecular weight components are expected to exhibit greater partitioning behavior to terrestrial media. Mobility in the aquatic and atmospheric environment is low due to low water solubility and low vapor pressure. These components will partition rapidly to the terrestrial compartment, where the main fate process is expected to be slow biodegradation of base oil components in soil and sediment.

A summary of the EQC modeling of the distribution and transport between environmental compartments for selected hydrocarbon compounds in lubricant base oils is presented in the attached table and graph. The compounds selected for modeling represent various C15 compounds in base oils (e.g., linear and branched paraffins, naphthenes and aromatic hydrocarbons).

<b>Result</b>	<b>Medium</b>	<b>% distribution</b>
	Air:	0 to 94
	Soil:	6 to 97
	Water:	0.88 to <0.0001
	Sediment	<0.1 to 2
	Suspended Sediment	<0.02 to 0.004

**Attached document** : See Attachment 2. EQC Modeling Results of the Distribution Between Environmental Compartments

**Conclusion** : See Attachment 3. Plot of the EQC Modeling Results of the Distribution Between Environmental Compartments  
: This complex petroleum mixture is expected to partition primarily to soil and/or sediment.

**Reliability** : (2) Valid with restrictions  
The predicted endpoint was determined using a validated computer model.

(72) (107)

### 3. Environmental Fate and Pathways

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

#### 3.5 BIODEGRADATION

**Type** : Aerobic  
**Inoculum** : Microorganisms were obtained from Canterbury Sewage Works (UK) and prepared according to the prescribed methods for this test.  
**Contact time** : 28 day(s)  
**Method** : Directive 84/449/EEC, C.5 "Biotic degradation - modified Sturm test"  
**Year** : 1986  
**GLP** : Yes  
**Test substance** : CAS No. 64742-65-0; Distillates (petroleum), solvent-dewaxed heavy paraffinic

**Result** : The test substance was partially degraded to 20-26% of the theoretical CO<sub>2</sub> in 28 days. Degradation commenced after a lag period of 2 days. Biodegradation curve showed that degradation had virtually stopped by day 28. Test substance was therefore inherently biodegradable since it achieved >20% biodegradability based upon CO<sub>2</sub> evolution.

<u>Sample</u>	<u>% Degradation (day 28)</u>	<u>Mean % Degraded</u>
Test substance	26, 20	23
Na Benzoate	86, 92	89

**Test condition** : The test substance was added to test medium from a stock solution containing 2.4 g/l emulsified in Dobane PT sulphonate (2 mg/l), a non-biodegradable detergent. The final test concentration of the base oil was 20 mg/l. The test medium was dispensed into Sturm vessels, inoculated and aerated with 60 ml/min of CO<sub>2</sub>-free air and incubated at 20 ± 1°C. Biodegradation was determined on days 1, 2, 5, 9, 14, 20, and 28 by titrating the total CO<sub>2</sub> released. The medium was acidified on day 27 to release the total CO<sub>2</sub> by day 28. Test substance, control blank, and sodium benzoate control (20 mg/l) were tested in duplicates. The empirical formula used was C<sub>n</sub>H<sub>2n+1</sub> which yielded a theoretical CO<sub>2</sub> evolution of 3.14 g CO<sub>2</sub> per g of test substance.

**Reliability** : (2) Valid with restrictions  
The study report lacked an extensive description of experimental procedures but instead referenced procedures detailed in a laboratory SOP.

(102)

**Type** : Aerobic  
**Inoculum** : Activated sludge, domestic  
**Contact time** : 28 day(s)  
**Method** : OECD Guide-line 301 F "Ready Biodegradability: Manometric Respirometry Test"  
**Year** : 1995  
**GLP** : Yes  
**Test substance** : CAS No. 64742-54-7; Distillates (petroleum), hydrotreated heavy paraffinic

**Result** : By day 28, 31% degradation of the test material was observed and indicated that the test material was inherently biodegradable.  
By day 5, >60% biodegradation of positive control was observed, which meets the guideline requirement. No excursions from the protocol were noted.

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Biodegradation was based on net oxygen consumption and the theoretical oxygen demand of the test material as calculated using results of an elemental analysis of the test material.

Sample	% Degradation* (day 28)	Mean % Degradation (day 28)
HHP	32.93, 27.2, 33.27	31.13
Na Benzoate	82.04; 72.88	77.46

\* replicate data

#### Test condition

: Fresh activated sludge was obtained one day prior to test initiation, and homogenized in a blender for two minutes. After allowing the sample to settle for approximately 30 minutes, the homogenated supernatant was decanted, avoiding carry-over of solids. Microbial activity of an aliquot of the filtered supernatant was  $1E^6$  CFU/ml which was determined using microbial agar dip slides. Activated sludge supernatant was added to the test medium at 10 ml/l and the inoculated medium was continuously aerated with CO<sub>2</sub>-free air until the next day when the test systems were prepared. Test medium consisted of glass distilled water and mineral salts (phosphate buffer, ferric chloride, magnesium sulfate, calcium chloride). Test vessels were 1 Liter glass flasks located in a water bath and electronically monitored for oxygen consumption. Test material was tested in triplicate, controls and blanks were tested in duplicate. Test material (hydrotreated heavy paraffinic petroleum distillates, HHP) concentration was approximately 44 mg/l, equivalent to a theoretical oxygen demand (ThOD) of 148 mg/l. Test material was weighed onto a Gelman type A/E 13 mm glass fiber filter which was then added to each respirometer flask. Sodium benzoate (positive control) concentration was 53.54 mg/l, and was added using an aliquot of a stock solution. Test temperature was  $22 \pm 1^\circ\text{C}$ . All test vessels were stirred constantly for 28 days using magnetic stir bars and plates.

#### Reliability

: (1) Valid without restriction

(83)

#### Type

: Aerobic

#### Inoculum

: Activated sludge, domestic

#### Contact time

: 28 day(s)

#### Method

: OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO<sub>2</sub> evolution)"

#### Year

: 1990

#### GLP

: Yes

#### Test substance

: CAS No. 64741-89-5; distillates (petroleum), solvent-refined, light paraffinic

#### Result

: By day 28, the 10 and 20 mg C/l test flasks showed biodegradation of 29% and 22%, respectively.

Day	% Degradation Reference	% Degradation 10 ppm Test Sub.	% Degradation 20 ppm Test Sub.
10	31	0	1
21	89	25	12
28	89	29	22

The test material was not readily biodegradable. Within a

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period of 28 days, 22 and 29% degradation was observed. The pass limit for this test is 60% within 28 days.

The reference test substance was degraded to 89% by day 28. The pH of the test cultures (10 mg/l and 20 mg/l) and controls (sodium benzoate standard and negative control) measured on Day 27 were 4.8, 4.8, 4.9, and 5.2, respectively.

- Test condition** : The test material entered the experimental containers through direct dispersion in water. Activated sludge bacteria from the Severn Trent Plc sewage treatment plant in Belper, Derbyshire was used as the inoculum. The sample sludge was homogenized in a mixer for 10 minutes prior to a solid settling phase and a subsequent filtering of the supernatant for use. The experimental containers had an inoculum concentration of 1%.
- The exposures lasted for a period of 28 days. The experimental containers were 5 liter glass culture vessels, containing 3 liters of a mixture of nutrient medium, test material, and inoculum. Test conditions were run in darkness at a constant temperature of 21°C. Nutrient medium was prepared according to the OECD guideline recipe using tap water purified by ion exchange and reverse osmosis. A series of both two controls and two test material concentrations were run. The controls consisted of a group with just the culture medium and the inoculum and a group with culture medium, inoculum, and 20 mg/l Sodium benzoate ( $C_6H_5 * COONa$ ). The two test concentrations of test material were 10 and 20 mg/l.
- All culture vessels were sealed and aerated with  $CO_2$  free air at a rate of about 2 bubbles per second. Additionally, the solution was continuously stirred by magnetic stirrers. Samples were taken from the first  $CO_2$  absorber vessel on Days 0, 1, 2, 3, 6, 8, 10, 14, 16, 21, 23, 27, and 28. Samples were taken from the second absorber vessel on Days 0 and 28. The absorbers were made up of 500 ml Dreschel bottles filled with 350 ml of 0.05M NaOH. The solution was prepared using purified, degassed water. On day 27, the pH of each vessel was measured and 1 ml of concentrated HCl was added to drive off inorganic carbonate.  $CO_2$  production (as inorganic carbon) was measured by an Ionics 555 TOC Analyzer in triplicate.
- Reliability** : (2) Valid with restrictions  
The study was performed following the 1981 guidelines for OECD 301B.

(32)

- Type** : Aerobic  
**Inoculum** : Activated sludge, domestic  
**Contact time** : 21 day(s)  
**Method** : CEC Method L-33-T-82 using test medium from ISO Standard 7827 and OECD 301A and 301E  
**Year** : 1991  
**GLP** : Yes  
**Test substance** : CAS No. 64741-89-5; distillates (petroleum), solvent-refined, light paraffinic

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**Result** : By day 21, biodegradation of the test substance was 63%, 65%, and 61% in the individual flasks. The mean biodegradation was 63%.

#### % Biodegradation

Reference Material				Test Substance		
Day	Rep1	Rep2	Rep3	Rep1	Rep2	Rep3
21	27	29	30	63	65	61

Mean: 29

63

Biodegradation of the reference material was 27%, 29%, and 30% in the individual flasks, and the mean biodegradation was 29%.

There were no apparent deviations from the given method.

**Test condition** : Settled activated sludge acquired from Buckland Sewage Treatment Works, Milber, Newton Abbot, Devon, was utilized as the inoculum. The inoculum was normally between  $10^5$  and  $10^7$  Colony Forming Units (CFU)/ml. Bacteria were enumerated by Dip Slide (Oxoid, TTC Red Spot) and incubated at  $25 \pm 1^\circ\text{C}$  until sufficient colonies were visible to enable counting.

The inoculum was used in the experiment at a rate of 1 ml per flask.

The test medium was prepared following the formula specified in ISO Standard 7827. Mother solutions of the test substance and reference oil were prepared by adding 150 g of test or reference substance to 1 liter of A113

(1,1,2-trichlorotrifluoroethane). The negative control reference substance was white oil, R.L. 110 (Brixham test substance #T071). The test design consisted of 5 test flasks containing 150 ml of test medium, 1 ml inoculum, and 50 ml of test substance mother solution; 5 reference flasks containing 150 ml of test medium, 1 ml inoculum, and 50 ml of reference substance mother solution; 2 blank flasks containing 150 ml of test medium and 1 ml inoculum; and 1 poisoned flask prepared identical as the test flasks but contained 1 ml of  $\text{HgCl}_2$ . Incubation flasks were 500-ml conical flasks fitted with foam plugs.

On day 0 of the test, two blank flasks, two test flasks, and two reference flasks were sacrificed for analysis of residual oil content by infrared spectrophotometry (see analysis procedure below). The remaining flasks were placed on an orbital incubator and maintained at  $25 \pm 1^\circ\text{C}$  for 21 days. On day 21, the contents of all flasks were analyzed for residual oil content.

#### Analysis Procedure:

Residual oil content (%) in each flask was analyzed using a method suitable for the determination of hydrocarbon lubricants in water samples. Lubricants were extracted from water using 1,1,2 trichlorotrifluoroethane and were analyzed using infrared spectrophotometry. The samples were quantified against known standards of the lubricant using the maximum absorption of the  $\text{CH}_3\text{-CH}_2$  band at  $2930 \pm 10 \text{ cm}^{-1}$ . Percent test substance degraded was calculated as

$$\frac{\% (\text{ROC}) \text{ poisoned flask} - \% \text{ ROC test flask}}{\% \text{ ROC poisoned flask}} \times 100$$

**Reliability** : (2) Valid with restrictions

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The CEC method is not a test of ready or inherent biodegradability, nor do the test results provide a reliable measure of the extent of ultimate biodegradability, or mineralization. These test results can only indicate primary biodegradation, i.e., some loss of oil based on concentration analysis of the parent base oil over the course of the study.

(55)

**Type** : Aerobic  
**Test substance** : Various base oils

**Remark** : 28 biodegradability studies have been reported for base oils. In the preceding paragraphs a full study description is given for each of the methods that have been used.

Based on the results of ultimate biodegradability tests using modified Sturm and manometric respirometry testing these base oils are expected to be, for the most part, inherently biodegradable.

Results of primary biodegradability testing using the CEC test method indicate that transformation of parent base oil due to biological activity occurs to a varying extent, ranging from 13% to 79% loss of original concentrations of tested base oils.

Summarized data for all studies (including those described in the preceding paragraphs) are tabulated below

Method*	Biodeg. (%)	Biodegradable Yes/No	Ref.
Distillates, solvent-refined heavy paraffinic (64741-88-4)			
OECD 301B**	22, 11	No	30
OECD 301B	15, 12	No	25
OECD 301B	8, 8	No	28
OECD 301B	3, 11	No	29
OECD 301B	12, 11	No	26
OECD 301B	9, 8	No	27
CEC L-33-T-82	72	Yes	57
CEC L-33-T-82	71	Yes	58
CEC L-33-T-82	53	Yes	49
CEC L-33-T-82	79	Yes	50
CEC L-33-T-82	64	Yes	59
CEC L-33-T-82	51	Yes	52
Distillates, solvent-refined light paraffinic (64741-89-5)			
OECD 301B	29, 22	No	32
OECD 301B	17, 17	No	33
CEC L-33-T-82	63	Yes	55
CEC L-33-T-82	75	Yes	56
Solvent de-asphalted Bright stock (64741-95-3)			
OECD 301B	11, 4	No	31
CEC L-33-T-82	17	No	54

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Distillates, hydrotreated or solvent refined light  
naphthenic (64741-97-5)

84\449\EEC, C5	1.5	No	103
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Solvent-refined residual oil (64742-01-4)

OECD 301B	4, 2	No	No Ref
OECD 301B	5, 5	No	44
CEC L-33-T-82	45	Yes	51
CEC L-33-T-82	13	No	53

Distillates, hydrotreated or solvent refined light  
naphthenic (64742-53-6)

OECD 301F	42	Yes	80
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Distillates, hydrotreated heavy paraffinic (64742-54-7)

OECD 301F	31	Yes	83
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Distillates, solvent dewaxed light paraffinic (64742-56-9)

OECD 301F	50	Yes	82
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Distillate, solvent-dewaxed heavy paraffinic (64742-65-0)

84\449\EEC, C5	23	Yes	102
OECD 301F	38	Yes	81

\* Methods used are:

OECD 301B	Ready, Sturm test
OECD 301F	Ready, Manometric method
CEC L-33-T-82	CEC Test
84\449\EEC, C5	Ready, Sturm Test

\*\* For method OECD 301B the two values given for  
biodegradation are for test material concentrations of 10  
and 20 ppm.

(25) (26) (27) (28) (29) (30) (31) (32) (33) (44) (49) (50) (51) (52) (53) (54) (55)  
(56) (57) (58) (59) (80) (81) (82) (83) (102) (103)

### 4.1 ACUTE/PROLONGED TOXICITY TO FISH

**Type** : Semi static  
**Species** : Salmo gairdneri (Fish, estuary, fresh water)  
**Exposure period** : 96 hour(s)  
**Unit** : mg/l  
**Limit test** : Yes  
**Analytical monitoring** : Yes  
**Method** : OECD Guide-line 203 "Fish, Acute Toxicity Test"  
**Year** : 1990  
**GLP** : Yes  
**Test substance** : CAS No. 64741-89-5; distillates (petroleum), solvent-refined, light paraffinic

**Result** : No mortality at 96 hours in the 0 and 1000 mg/l groups.

96 hrs-LL<sub>0</sub> = 1000 mg/l, based on nominal loading rates.

**Test condition**

: Only one concentration was tested in the limit test. The report states that water samples were taken at 0, 24, and 96 hours for analytical verification of test concentrations, but results of any analyses were not reported.

: Daily renewal of the test media ensured that test material levels were maintained at the exposure concentrations. The test media was introduced into the exposure vessels through direct dispersion in water. Shielded propeller-stirrers were utilized to aid in the dispersion of the test material. Observations indicated that the test material was well dispersed throughout the experiment. 20 ml water samples were drawn from the exposure vessels via a glass syringe and delivered to a storage vessel. The syringe was then rinsed with 20 ml of 1,1,2-trichlorotrifluoroethane. Subsequently, the rinse was mixed with the sample prior to storage. Water samples were collected at 0, 24, and 96 hours into the experiment. Samples were stored at 4°C in glass containers until BP International Limited analyzed them. Exposure vessels were glass aquaria equipped with shielded propeller-stirrers containing 20 liters of test media. The stirrers rotated at 2000 rpm. 10 fish were housed in each vessel and 20 fish were exposed at the experimental concentration. The experimental groups included a control and a group exposed to a concentration of 1000 mg/l. The exposure was conducted under a 16 hour/8 hour, light/dark photoperiod. The rainbow trout were supplied by Trafalgar Nurseries, Downton, Salisbury, U.K. The mean length and mean weight (sd) of the experimental fish were 4.8 cm (0.4 cm) and 1.33 g (0.49 g), respectively. Fish were fed commercial trout pellets on a daily basis. Feeding was discontinued 24 hours prior to the initial exposure. The fish were laboratory acclimated for 4 days prior to a one week test condition acclimation. Biomass loading in the test chambers was 0.67 g/l. Test water was tap water, dechlorinated through the addition of sodium thiosulfate. Exposures occurred at 14°C, a hardness of 50 mg/l as CaCO<sub>3</sub> and the D.O. level never

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<b>Reliability</b>	: dropped below 10.0 mgO <sub>2</sub> /l. The pH of the control groups ranged from 7.6-7.7. (2) Valid with restrictions Only one concentration of the test substance was tested. Results of chemical analyses of test substance concentrations were not reported.	(42)
<b>Method</b>	: Acute toxicity tests	
<b>Test substance</b>	: Various base oils	
<b>Remark</b>	: Acute fish toxicity studies have been reported for 14 base oil samples (including the study summarized in full above). The results for all 14 samples are summarized in the table below.	

<u>Result</u>	<u>Reference</u>
Salmo gairdneri - semistatic test	
Distillates, solvent-refined heavy paraffinic (64741-88-4)	
7-d LL <sub>0</sub> =1000 ppm dispersion	48
7-d LL <sub>0</sub> =1000 ppm dispersion	40
7-d LL <sub>0</sub> =1000 ppm dispersion	38
7-d LL <sub>0</sub> =1000 ppm dispersion	39
7-d LL <sub>0</sub> =1000 ppm dispersion	46
7-d LL <sub>0</sub> =1000 ppm dispersion	60
Distillates, solvent refined light paraffinic (64741-89-5)	
96-h LL <sub>0</sub> =1000 ppm dispersion	42
7-d LL <sub>0</sub> =1000 ppm dispersion	45
Solvent deasphalted bright stock (64741-95-3)	
96-h LL <sub>0</sub> =1000 ppm dispersion	47
Solvent refined residual oil (64742-01-4)	
7-d LL <sub>0</sub> =1000 ppm dispersion	43
96-h LL <sub>0</sub> =1000 ppm dispersion	41
Pimephales promelas - static test	
Distillates hydrotreated heavy paraffinic (64742-54-7)	
96-h LL <sub>0</sub> =100 ppm WAF	78
Solvent dewaxed residual oil (64742-62-7)	
96-h LL <sub>0</sub> =100 ppm WAF	79
Distillates solvent dewaxed heavy paraffinic (64742-65-0)	
96-h LL <sub>0</sub> =100 ppm WAF	77
(38) (39) (40) (41) (42) (43) (45) (46) (47) (48) (60) (77) (78) (79)	

### 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

<b>Type</b>	: Static
<b>Species</b>	: Daphnia magna (Crustacea)
<b>Exposure period</b>	: 48 hour(s)
<b>Unit</b>	: mg/l

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**Analytical monitoring** : No  
**Year** : 1988  
**GLP** : No  
**Test substance** : CAS No. 64742-53-6 or 64741-97-5, Distillates (petroleum), hydrotreated or solvent-refined light naphthenic

**Result** : After 48 hrs no daphnid immobilization was found in any of the concentrations tested.

The 48 hr  $EL_0$  was 10 g/l.

**Test condition** : Control survival was 100% after 48 hrs.  
Individual treatment concentrations were prepared as water accommodated fractions (WAF). Nominal loading rates in the definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control and dilution water was reconstituted hard water prepared by adding salts to glass-distilled deionized water following EPA guidelines (hardness 174 mg/ml as  $CaCO_3$ ). Test substance was mixed in dilution water for 23 hrs. The mixtures were allowed to stand for 1 hr prior to siphoning off the aqueous phase for testing. Glass flasks (140 ml) were filled with each of the WAFs with 10 daphnids per vessel. The flasks were sealed with glass cover slip to minimize the loss of volatile components of the oil. Test daphnids were <24 hrs old and collected from cultures supplied by the testing laboratory that have been aged between 15 and 35 days. Two replicates per treatment and control were used. Black caps were placed over those flasks in which an oily film was visible on the surface of the test solution so the organisms would avoid the darkened zone and not be trapped in the film. Test temperature was 18 - 22 °C. Dissolved oxygen in the control and highest concentration was 8.8 to 9.1 mg/ml. pH in the control and highest concentration was 7.7 - 8.0.

**Reliability** : (2) Valid with restrictions  
Although test guidelines were not specified and the study was not conducted under GLPs, it was a well-documented study. Analytical monitoring of the oil concentration in the WAFs was not performed. An oily film was visible on the surface of some test solutions apparently as a carryover from the WAF preparations.

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**Type** : Semi static  
**Species** : Gammarus pulex (Crustacea)  
**Exposure period** : 96 hour(s)  
**Unit** : mg/l  
**Analytical monitoring** : No  
**Year** : 1988  
**GLP** : No  
**Test substance** : CAS No. 64742-53-6 or 64741-97-5, Distillates (petroleum), hydrotreated or solvent-refined light naphthenic

**Result** : No dead organisms were found in any of the test vessels after 96 hours. However, some organisms disappeared from all treatments and control throughout the test. It was assumed that these organisms were eaten by the remaining organisms. The numbers of missing animals after 96 hours were 2, 1, 4,

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- 5, and 2 in the control, 0.01, 0.1, 1, and 10 g/l WAFs. Since <50% of the organisms were missing in any concentration, and even if these lost animals died as a result of treatment, the 96-hr  $LL_0$  was 10 g/l.
- Test condition** : Individual treatment concentrations were prepared as water accommodated fractions (WAF). Nominal loading rates in the definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control and dilution water was laboratory mains tap water obtained from bore holes, and passed through particle and activated carbon filters (alkalinity 247 mg/ml as  $CaCO_3$ , hardness 274 mg/ml as  $CaCO_3$ , conductivity 492 mS/cm, pH 7.3). Test substance was mixed in dilution water for 23 hrs. The mixtures were allowed to stand for 1 hr prior to siphoning off the aqueous phase for testing. Fresh WAFs were prepared for each 24-hr renewal. Glass crystallizing dishes (350 ml) were filled with 300 ml of each of the WAFs with 10 organisms per dish. Three replicates per treatment and control were used. Test organisms were between 1 and 2 mm in size and collected from a tributary of the River Len at Hollingbourne, Kent, UK. Test temperature was 14 - 18.2 °C. Dissolved oxygen in the control and highest concentration was 7.8 to 9.9 mg/ml. pH in the control and highest concentration was 6.8 - 8.5.
- Reliability** : (2) Valid with restrictions  
Although test guidelines were not specified and the study was not conducted under GLPs, it was a well-documented study. Analytical monitoring of the oil concentration in the WAFs was not performed.

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### 4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

- Species** : *Scenedesmus subspicatus* (Algae)  
**Endpoint** : Growth rate  
**Exposure period** : 96 hour(s)  
**Unit** : mg/l  
**Limit test** : Yes  
**Analytical monitoring** : Yes  
**Method** : OECD Guide-line 201 "Algae, Growth Inhibition Test"  
**Year** : 1991  
**GLP** : Yes  
**Test substance** : CAS No. 64741-88-4; distillates (petroleum), solvent-refined, heavy paraffinic

- Remark** : Three other base oil samples have been tested for algal toxicity.  
The results for all three samples were similar to that described above.  
Samples tested at one concentration only were as follows:

CAS No.	Result	Ref.
64741-88-4	96-h $LL_0$ = 50% WAF	34
64741-89-5	96-h $LL_0$ = 50% WAF	35
64742-01-4	96-h $LL_0$ = 50% WAF	37

- Result** : No inhibition of growth or growth rate were measured at the single test concentration of 50% WAF.

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### Test condition

Since there were no observed effects during the study, the 96-hour "No Observed Effect Concentration" (NOEC) was 50% WAF.

The OECD guideline criterion for cell growth in the control group was met in this experiment.

: Preparation of the Water Accommodated Fraction (WAF): 2.0 grams of test material were placed on 2 Liters of culture medium and stirred via magnetic stirrer for a period of 24 hours prior to the test. Culture medium was prepared according to the guideline formula. After the 24 hour period, stirring was ceased for one hour prior to removing the aqueous phase. The aqueous phase, representing 100% WAF, was then combined with an equal volume of algal suspension. The algal suspension consisted of *Scenedesmus* cells taken from a culture in logarithmic growth phase and diluted with growth medium to a cell density of  $3.70 \times 10^4$  cells/ml. The algal species *Scenedesmus subspicatus* utilized in this study was supplied by the Culture Centre of Algae and Protozoa (CCAP) c/o Institute of Freshwater Ecology, Cumbria, U.K. Sterile culture medium was inoculated with *Scenedesmus* and incubated under continuous illumination and aeration at 21°C.

10 ml samples of the 50% WAF were taken at times 0 and 96 hours. After adding 10 ml of 1,1,2-trichlorotrifluoroethane, the samples were stored at 4°C until analyzed. Analytical results were not reported. 500 ml of the algal suspension were added to 500 ml of 100% WAF to make the test solution. 100 ml of the test solution was contained in a loosely stoppered 250 ml conical flask. All flasks were incubated and shaken at approximately 100 rpm in an orbital shaker. 6 replicates of a single test concentration and 3 replicates of a control were examined in this study. The flasks were housed under a 24 hour light photoperiod at an intensity of approximately 7,000 lux and a constant temperature of 24°C. No aeration was supplied during the study, however, gas exchange and algal cell suspension was maintained by the orbital shaker. Samples were taken for the determination of algal growth every 24 hours beginning at hour 0 and ending at hour 96. Absorbances were measured at 665 nm with a Jenway 610 Spectrophotometer. At the initiation and completion of the experiment, the cell densities of the control cultures were determined through direct counting aided by a hemacytometer. The pH of all control and test flasks was taken at 0 and 96 hours. The pH at the beginning and end of the experiment in all groups ranged from 8.3 to 8.5 and 9.4 to 9.9, respectively. The area under the curve and growth rate were taken as indices of algal growth and were calculated using the absorbance readings. Percent inhibition values were calculated for area under the curve and growth rate.

### Reliability

: (2) Valid with restrictions  
Only one concentration of the test substance was tested. Results of chemical analyses of test substance concentrations were not reported.

(34) (35) (36) (37)

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### 4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

**Species** : Daphnia magna (Crustacea)  
**Endpoint** :  
**Exposure period** : 21 day(s)  
**Unit** : mg/l  
**Analytical monitoring** : Yes  
**Method** : OECD Guide-line 202, part 2 "Daphnia sp., Reproduction Test"  
**Year** : 1995  
**GLP** : Yes  
**Test substance** : CAS No. 64741-88-4; distillates (petroleum), solvent-refined, heavy paraffinic

**Result** : After 14 and 21 days of exposure, there were no statistically significant differences between the control group and the 10 and 1000 mg/ml WAF test groups in terms of survival or reproduction (young produced per adult). In addition, there were no apparent effects on the F1 generation produced during the test. The numbers of unhatched eggs and dead young were low in all treatment groups.

The NOEC for survival and reproduction was the maximum test concentration, 1000 mg/ml WAF.

The test met the validation criteria for 1) dissolved oxygen at least 60%, 2) pH deviation not greater than 0.3, 3) control mortality not greater than 20%, 4) first young (control group) within 9 days, 5) cumulative young per female (control group) at least 20 after 14 days and at least 40 after 21 days, and 6) number of broods per control group at least 3.

**Test condition** : Preparation of the WAF:  
20 and 2000 mg of test material were each separately placed in 2 liters of reconstituted water (water hardness approximately 270 mg/ml as CaCO<sub>2</sub>) and stirred via magnetic stirrer for a period of 24 hours prior to the test. After the 24-hour period, stirring was ceased for one hour prior to removing the aqueous phase.

#### Test Organism Culture:

Adult Daphnia magna were maintained in polypropylene vessels containing approximately 2 liters of reconstituted water at a

temperature of 21°C. The organisms were supplied by the Institut National de Recherche Appliquée (IRCHA) France.

The lighting was held at 16:8 hour light:dark photoperiods. Gravid adults were isolated 24 hours prior to the initiation of the test, the young daphnids produced overnight were removed and utilized for testing.

#### Test Procedure:

The aqueous phase of each WAF was removed and 400-ml aliquots were apportioned to five, 500-ml glass flasks. A similar number of control flasks containing reconstituted water also were prepared. The fifth flask from each group was taken for Total Organic Carbon analysis of the exposure

## 4. Ecotoxicity

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media. At the start of the test, 10 daphnids were placed within each test flask, and all flasks were covered to reduce evaporation. Each vessel received approximately  $3.75 \times 10^9$  cells/ml of a mixed unicellular algae culture as a daily feeding. Fresh WAFs were prepared on days 0, 2, 4, 7, 9, 11, 14, 16, and 18, and the adult daphnids were transferred from the old to the fresh solutions. The numbers of live and dead *Daphnia* of the parental generation were counted daily. At each test media renewal, *Daphnia* with eggs or young in the brood pouch, discarded unhatched eggs, and the number of live and dead filial *Daphnia* were counted.

Temperature was recorded daily for the duration of the experiment, while dissolved oxygen and pH were recorded prior to and after each media renewal. Measurements of TOC were made in the fresh and old test solutions 3 times a week over 21 days. Dissolved oxygen in the control, 10, and 1000 mg/ml WAF groups ranged from 7.9 to 8.3, from 7.9 to 8.3, and from 7.8 to 8.3, respectively. Water pH in the control, 10, and 1000 mg/ml WAF groups ranged from 7.7 to 7.8, from 7.7 to 7.8, and from 7.7 to 7.8, respectively. The temperature within all test groups remained constant at 21.0 °C. The results of the TOC analysis did not demonstrate a direct relationship with WAF concentration, and in many cases the TOC of the control water was higher than that of the test groups. The TOC in the old media tended to be higher than fresh solutions.

**Reliability** : (2) Valid with restrictions  
The analytical results provided no definitive evidence of stability of the test preparations. Only two test concentrations were run.

(62)

**Species** : *Daphnia magna* (Crustacea)  
**Exposure period** : 21 day(s)  
**Unit** : mg/l

**Remark** : In addition to the study described above studies have been reported for ten further base oil samples in 21 day studies with *D. magna*. In each case OECD guideline 202 part 2 was used as the method.  
The results are summarized below:

CAS No.	Result	Reference
64741-88-4	21-d LL <sub>0</sub> = 1000 mg/l WAF	63
64741-88-4	21-d LL <sub>0</sub> = 1000 mg/l WAF	64
64741-88-4	21-d LL <sub>0</sub> = 1000 mg/l WAF	100
64741-89-5	21-d LL <sub>0</sub> = 1000 mg/l WAF	67
64741-89-5	21-d LL <sub>0</sub> = 1000 mg/l WAF	61
64741-95-3	21-d LL <sub>0</sub> = 1000 mg/l WAF	66
64742-01-4	21-d LL <sub>0</sub> = 1000 mg/l WAF	65
64742-53-6	21-d LL <sub>0</sub> = 10 mg/l WAF	101
64742-55-8	21-d LL <sub>0</sub> = 1000 mg/l WAF	100
64742-65-0	21-d LL <sub>0</sub> = 1000 mg/l WAF	100

Of the reported chronic toxicity studies, no chronic effects

## 4. Ecotoxicity

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were observed below 1 mg/l. For all but two studies, no chronic toxicity was seen at the highest addition of the various base oils tested, which ranged from 1000 to 5000 mg/l.

(61) (63) (64) (65) (66) (67) (100) (101)

## 5. Toxicity

**Id** Lubricating Oil  
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### 5.1.1 ACUTE ORAL TOXICITY

**Type** : LD<sub>50</sub>  
**Value** : > 5000 mg/kg bw  
**Species** : Rat  
**Strain** : Sprague-Dawley  
**Sex** : Male/female  
**Number of animals** : 5  
**Vehicle** : None - administered undiluted  
**Year** : 1986  
**GLP** : Yes  
**Test substance** : Unrefined base oil, Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.

**Method** : A single dose of undiluted test material (5g/kg) was administered orally to 5 male and 5 female fasted rats. Food and water was made available ad-lib immediately after dosing.

The animals were observed for clinical signs and mortality at hourly intervals for the first 6 hours post dosing and twice daily thereafter. Body weights were recorded prior to fasting, prior to dosing and at 7 and 14 days post dosing. At 14 days, all surviving animals were killed and subjected to a gross necropsy examination.

**Result** : There were no deaths during the study and growth rates were unaffected by dosing. Clinical signs that occurred during the first 3 days included: hypoactivity, diarrhea and a yellow-stained anal area. All animals returned to normal by day 14. At gross necropsy, there were no visible lesions.

**Reliability** : (1) Valid without restriction

(12)

**Type** : LD<sub>50</sub>  
**Value** : > 5000 mg/kg bw  
**Species** : Rat  
**Strain** : Sprague-Dawley  
**Sex** : Male/female  
**Number of animals** : 5  
**Vehicle** : Non - administered undiluted  
**Year** : 1986  
**GLP** : Yes  
**Test substance** : Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See section 1.1.1.

**Method** : A single dose of undiluted test material (5g/kg) was administered orally to 5 male and 5 female fasted rats. Food and water was made available ad-lib immediately after dosing.

The animals were observed for clinical signs and mortality at hourly intervals for the first 6 hours post dosing and twice daily thereafter. Body weights were recorded prior to fasting, prior to dosing and at 7 and 14 days post dosing. At 14 days, all surviving animals were killed and subjected to a gross necropsy examination.

**Result** : There were no deaths during the study. Clinical signs observed included: hypoactivity,

## 5. Toxicity

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yellow-stained anal area, hair loss in the urogenital region and swollen hind paws.  
All animals returned to normal by day 3 and had gained weight by day 7.  
At necropsy, there were no visible lesions except in one female in which the spleen was cystic, mottled red and tan and had a rough surface. In this animal the pancreas adhered to the entire surface of the spleen.

**Reliability** : (1) Valid without restriction (11)

**Type** : LD<sub>50</sub>  
**Species** : Rat  
**Test substance** : Various Base oils

**Remark** : CONCAWE summarized the data available on the acute oral toxicity of lubricating oil base stocks. The data are shown in the following table.

CAS No.		Oral LD <sub>50</sub> (g/kg)	API Report No
<b>Paraffinic distillates</b>			
Solvent dewaxed, light			
API 78-9	64742-56-9	>5	29-33104
Solvent dewaxed, heavy			
API 78-10*	64742-56-0	>5	29-33105
API 79-3	64742-65-0	>5	29-33067
API 79-4	64742-65-0	>5	29-33066
API 79-5	64742-65-0	>5	29-33068
White mineral oil			
Tufflo 6056*		>5	39-31651
<b>Naphthenic distillates</b>			
Solvent refined, light			
API 78-5	64741-97-5	>5	29-33106
Solvent refined, heavy			
API 79-1	64741-96-4	>5	29-33065
Hydrotreated, heavy			
API 83-15	64742-52-5	>5	33-32639

\* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information.  
(2) (3) (4) (5) (6) (7) (8) (13) (71)

### 5.1.2 ACUTE INHALATION TOXICITY

**Type** : LC<sub>50</sub>  
**Value** : 2.18 mg/l

## 5. Toxicity

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

**Species** : Rat  
**Strain** : Sprague-Dawley  
**Sex** : Male/female  
**Number of animals** : 5  
**Vehicle** : Air  
**Exposure time** : 4 hour(s)  
**Year** : 1987  
**GLP** : Yes  
**Test substance** : Highly refined Base oil Sample API 83-12 [CAS64742-53-6]  
See section 1.1.1.

**Method** : A group of 5 male and 5 female rats were exposed for 4 hours to an aerosol of the test material at a target concentration of 5 mg/l. Four additional groups of rats were then exposed for 4 hours to target aerosol concentrations of 1, 1.5, 2.5 and 3.5 mg/l. A control group exposed, in the chamber, to air only was also included.  
Animals were observed continuously during the first hour of exposure, hourly for the remainder of the exposure and once daily for the 14-day post exposure period. Mortalities were recorded and body weights were measured prior to exposure and again 7 and 14 days after exposure. On the 14th day post-exposure, necropsies were performed on all surviving animals. For all animals, including animals found dead, the lungs and any other abnormal tissues were removed and fixed for subsequent histopathological examination.

**Result** : Actual exposure concentrations and mortalities were as follows:

<b>Target level (mg/l)</b>	<b>Actual concentration mg/l    ±SD</b>		<b>Mortality Male    Female</b>	
0	0.02	0.01	0/5	0/5
1.0	1.04	0.1	1/5	1/5
1.5	1.51	0.15	0/5	0/5
2.5	2.37	0.31	3/5	3/5
3.5	3.49	0.36	5/5	5/5
5.0	5.05	0.18	5/5	5/5

Particle size measurements confirmed that mass median aerodynamic diameter and geometric standard deviation values were in the ranges 1.7 to 2.5 µm and 1.5 to 1.61 respectively. These measurements confirm that the particles were within the respirable range.

The LC<sub>50</sub> for combined sexes was estimated to be 2.18 with 95% confidence limits of 1.80 to 2.55 mg/l.

Body weight differences did not show a consistent dose related pattern.

At the highest concentration, the animals were obscured by a dense aerosol and observations could not be made during the exposure period. In other groups, there was a decreased activity, wet inguinal area, eyes partially closed, wet coat, loose stool and oily coat during exposure. During the first week post-exposure, similar signs were observed as well as signs of poor condition, respiratory distress and some deaths occurred. During test week 2, most

## 5. Toxicity

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survivors were considered to be of normal appearance. The signs that were observed occurred in a dose related manner.

At gross necropsy, dark red lungs were described for some animals. The incidence is shown below.

<b>Dose group</b>	<b>Male</b>	<b>Female</b>
0	0/5	0/5
1.0	1/5	1/5
1.5	0/5	0/5
2.5	3/5	3/5
3.5	5/5	5/5
5.0	5/5	5/5

At histology, affected animals exhibited diffuse pulmonary congestion and perivascular edema that were mostly moderate or marked in degree. Less consistently spotty alveolar edema was also seen. There was widespread damage to alveolar walls resulting in fibronecrotic debris resembling hyaline membranes in more marked cases and extravasation of RBCs and PMNs. Necrosis and inflammation were seen in the walls of small blood vessels and there was spotty epithelial necrosis in small bronchioles, but the most severe damage seemed to be centroacinar. The larger airways were relatively unaffected.

None of the surviving animals exhibited the above acute changes. However, most of the surviving animals exposed to 2.5 or 1.0 mg/l and above exhibited chronic inflammatory changes that were not seen in the controls and only occasionally in animals exposed at the 1.5 mg/l level, and then to a lesser degree of severity.

Other findings were considered sporadic or unrelated to exposure to the test material.

**Test condition** : Whole body exposures were carried out in stainless steel and glass chambers of 0.25 cubic meter volume. Aerosols were generated using a nebulizer. Concentrations of test material in the exposure chambers were determined gravimetrically by collection of the aerosol on filters. Analytical samples were taken at least once per hour during the exposure period. Particle size determinations were also carried out.

**Reliability** : (1) Valid without restriction

(15)

**Type** : LC<sub>50</sub>

**Species** : Rat

**Test substance** : Various Base oils

**Remark** : CONCAWE summarized the data available on the acute inhalation toxicity of lubricating oil mists in 4 hour exposure studies in rats. The data (Original source Whitman et al, 1989) on 3 paraffinic distillates are shown in the following table.

**Inhalation LC<sub>50</sub>**

## 5. Toxicity

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	(mg/l)
Paraffinic distillates	
Solvent extracted, dewaxed	>4
Solvent extracted, dewaxed, hydrotreated	>4
Solvent dewaxed, light	>4

(71) (111)

### 5.1.3 ACUTE DERMAL TOXICITY

**Type** : LD<sub>50</sub>  
**Value** : > 2000 mg/kg bw  
**Species** : Rabbit  
**Strain** : New Zealand white  
**Sex** : Male/female  
**Number of animals** : 4  
**Vehicle** : None applied undiluted  
**Year** : 1986  
**GLP** : Yes  
**Test substance** : Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.

**Method** : Undiluted test material was applied as a single dose (2g/kg) to the shorn, abraded skin of 4 male and 4 female rabbits. The treated site was covered with an occlusive dressing for 24 hours. After removal of the dressing, the skin was wiped with a wet towel to remove residual test material. The rabbits were observed for clinical signs and mortality hourly for the first 6 hours, then daily for dermal irritation and twice daily for clinical signs and mortality. Observation was carried out for a 14-day post treatment period. Body weights were recorded prior to administration of the test material, again 7 days post dosing and at study termination (14 days). At termination, all surviving animals were killed and subjected to a gross necropsy examination.

**Result** : There were no mortalities during the study. With the exception of skin irritation, there were no clinical signs of toxicity except that on day 4 soft stool was observed in 1 male and 3 female animals. Dermal irritation ranged from slight to severe for erythema and edema, from slight to marked for fissuring and slight to moderate for atonia and desquamation. Slight coriaceousness was also observed. Body weight losses were recorded for 2 male and 3 female animals at day 7. One male was less than starting weight on both day 7 and day 14.

**Reliability** : (1) Valid without restriction

(12)

**Type** : LD<sub>50</sub>  
**Value** : > 2000 mg/kg bw  
**Species** : Rabbit  
**Strain** : New Zealand white  
**Sex** : Male/female  
**Number of animals** : 2  
**Vehicle** : None - applied undiluted  
**Year** : 1986  
**GLP** : Yes

## 5. Toxicity

**Id** Lubricating Oil  
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**Test substance** : Highly refined Base oil Sample API 83-12 [CAS64742-53-6]  
See section 1.1.1.

**Method** : Undiluted test material was applied as a single dose (2g/kg) to the shorn, abraded skin of 4 male and 4 female rabbits. The treated site was covered with an occlusive dressing for 24 hours. After dressing removal, the skin was wiped with a wet towel to remove residual test material. The rabbits were observed for clinical signs and mortality hourly for the first 6 hours, then daily for dermal irritation and twice daily for clinical signs and mortality. Observation was carried out for a 14-day post treatment period. Body weights were recorded prior to administration of the test material, again 7 days post dosing and at study termination (14 days). At termination, all surviving animals were killed and subjected to a gross necropsy examination.

**Result** : There were no deaths during the study.  
The only clinical observation with the exception of skin irritation was soft stool in all animals. This was observed 3 hours after dosing and returned to normal by day 2. Skin irritation was observed in all animals and ranged from slight to severe for erythema and edema, from slight to marked for atonia, desquamation and fissuring and from slight to moderate for coriaceousness. Other dermal irritation seen included blanching and subcutaneous hemorrhage.  
All animals had gained weight by the end of the study. At necropsy, except for the skin lesions no other visible lesions were recorded.

**Reliability** : (1) Valid without restriction

(11)

**Type** : LD<sub>50</sub>  
**Species** : Rabbit  
**Test substance** : Various Base oils

**Remark** : CONCAWE summarized the data available on the acute dermal toxicity of lubricating oil base stocks in rabbits. The data are shown in the following table.

	CAS No	Dermal LD <sub>50</sub> (g/kg)	API Report No.
<b>Paraffinic distillates</b>			
Solvent dewaxed, light			
API 78-9	64742-56-9	>5	29-33104
Solvent dewaxed, heavy			
API 78-10*	64742-56-0	>5	29-33105
API 79-3	64742-65-0	>5	29-33067
API 79-4	64742-65-0	>5	29-33066
API 79-5	64742-65-0	>5	29-33068

### Naphthenic distillates

Solvent refined, light			
API 78-5	64741-97-5	>5	29-33106

## 5. Toxicity

**Id** Lubricating Oil  
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Solvent refined, heavy API 79-1	64741-96-4	>5	29-33065
Hydrotreated, heavy API 83-15	64742-52-5	>2	33-32639

\* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information  
(2) (3) (4) (5) (6) (7) (8) (13) (71)

### 5.2.1 SKIN IRRITATION

**Species** : Rabbit  
**Concentration** : Undiluted  
**Exposure** : Occlusive  
**Exposure time** : 24 hour(s)  
**Number of animals** : 6  
**Vehicle** : None - undiluted  
**PDII** : 4.3  
**Result** : Moderately irritating  
**Method** : Draize Test  
**Year** : 1986  
**GLP** : Yes  
**Test substance** : Unrefined base oil, Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.

**Method** : 0.5 ml of undiluted test material was applied to the shorn dorsal skin in two areas on each of 6 male rabbits. One area was intact and the other abraded skin. The treated area was then covered with an occlusive dressing. After 24 hours, the dressing was removed and the treated skin was wiped to remove any residue of test material. The degree of erythema and edema was recorded according to the Draize scale. A second reading of skin responses was made at 72 hours and again at 96 hours, 7 and 14 days. Results of the 24 and 72-hour readings were used to determine the Primary Irritation Index.

**Result** : One animal died on day 10 even though there had been no signs of ill health previously. Irritation scores given below are averages from 5 animals.

Observation period	Erythema		Edema		Average Score
	Intact	Abraded	Intact	Abraded	
24 hrs.	2.3	2.5	2.3	2.3	4.8
72 hrs.	1.8	2.0	1.7	2.0	3.8
96 hrs.	1.5	1.7	1.0	1.0	2.6
7 days	0.3	0.3	0.3	0.5	0.8
14 days	0	0	0	0	0

**Reliability** : Primary dermal irritation index: 4.3  
(1) Valid without restriction

(12)

**Species** : Rabbit  
**Concentration** : Undiluted

## 5. Toxicity

**Id** Lubricating Oil  
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**Exposure** : Occlusive  
**Exposure time** : 24 hour(s)  
**Number of animals** : 6  
**Vehicle** : None - undiluted  
**PDII** : 5.4  
**Result** : Moderately irritating  
**Method** : Draize Test  
**Year** : 1986  
**GLP** : Yes  
**Test substance** : Highly refined Base oil, Sample API 83-12 [CAS64742-53-6]  
See section 1.1.1.

**Method** : 0.5 ml of undiluted test material was applied to the shorn skin in two areas on each of 6 male rabbits. One area was intact and the other abraded skin. The treated area was then covered with an occlusive dressing.  
After 24 hours, the dressing was removed and the treated skin was wiped to remove any residue of test material. The degree of erythema and edema was recorded according to the Draize scale. A second reading of skin responses was made at 72 hours and again at 96 hours, 7 and 14 days. Results of the 24 and 72-hour readings were used to determine the Primary Irritation Index.

**Result** : Average Irritation scores are given below:

<u>Observation period</u>	<u>Erythema</u>		<u>Edema</u>		<u>Average Score</u>
	<u>Intact</u>	<u>Abraded</u>	<u>Intact</u>	<u>Abraded</u>	
24 hrs.	2.3	2.3	2.7	2.7	5.0
72 hrs.	3.0	3.0	2.5	3.0	5.8
96 hrs.	2.7	2.8	2.7	3.0	5.6
7 days	1.3	2.2	0.8	1.7	3.0
14 days	0	0	0	0	0

**Reliability** : Primary dermal irritation index: 5.4  
(1) Valid without restriction

(11)

**Species** : Rabbit  
**Concentration** : Undiluted  
**Exposure time** : 24 hour(s)  
**Test substance** : Various base oils

**Remark** : CONCAWE summarized the data available on skin irritation for the lubricating oil base stocks. The data are shown in the following table.

	<u>Irritation*</u>	<u>API Report</u>
<b>Paraffinic distillates</b>		
Solvent dewaxed, light API 78-9 (64742-56-9)	Slight (0.6)	29-33104
Solvent dewaxed, heavy		

## 5. Toxicity

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

API 78-10*** (64742-56-0)	Non (0.27)	29-33105
API 79-3 (64742-65-0)	Non (0.33)	29-33067
API 79-4 (64742-65-0)	Non (0.34)	29-33066
API 79-5 (64742-65-0)	Non (0.38)	29-33068

**White mineral oil\*\*\*** Slight Hoekstra & Phillips

### Naphthenic distillates

Solvent refined, light		
API 78-5 (64741-97-5)	Slight (0.65)	29-33106
Solvent refined, heavy		
API 79-1 (64741-96-4)	Slight (0.8)	29-33065
Hydrotreated, heavy		
API 83-15 (64742-52-5)	Slight (1.3)**	33-32639

\* Irritation described as slight, moderate or non-irritating in the original reports (Mean irritation score given in parentheses)

\*\* Irritation index

\*\*\* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information

(2) (3) (4) (5) (6) (7) (8) (13) (71)

### 5.2.2 EYE IRRITATION

**Species** : Rabbit  
**Concentration** : Undiluted  
**Dose** : .1 ml  
**Number of animals** : 9  
**Method** : Draize Test  
**Year** : 1986  
**GLP** : Yes  
**Test substance** : Unrefined base oil, Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.

**Method** : 0.1 ml of undiluted test material was applied to the corneal surface of one eye of each of 9 rabbits, the other eye was untreated and served as control.  
 After 20 to 30 seconds, the treated eyes of 3 rabbits were washed with lukewarm water for 1 minute. Eyes of the other 6 rabbits were not washed.  
 Readings of ocular lesions for all animals were made at 1, 24, 48, 72 hours and 7 days after treatment. Sodium fluorescein was used to aid in revealing possible corneal injury.

**Result** : One animal died on day 7 but this was not considered to be treatment related.  
 The test material did not cause a pain response, corneal or iridial irritation. The eye irritation that occurred had cleared by 48 hours.  
 The primary eye irritation scores (according to the standard Draize scoring procedure) were as follows:

## 5. Toxicity

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

	<b>Period</b>	<b>Unwashed eyes</b>	<b>Washed eyes</b>
	1 hour	3.0	4.0
	24 hours	1.7	0
	Scores of 0 were recorded at all other observation times.		
<b>Reliability</b>	: (1) Valid without restriction		

(12)

<b>Species</b>	: Rabbit
<b>Concentration</b>	: Undiluted
<b>Dose</b>	: .1 ml
<b>Number of animals</b>	: 9
<b>Method</b>	: Draize Test
<b>Year</b>	: 1986
<b>GLP</b>	: Yes
<b>Test substance</b>	: Highly refined Base oil, Sample API 83-12 [CAS64742-53-6] See section 1.1.1.

<b>Method</b>	: 0.1 ml of undiluted test material was applied to the corneal surface of one eye of each of 9 rabbits, the other eye was untreated and served as control. After 20 to 30 seconds, the treated eyes of 3 rabbits were washed with lukewarm water for 1 minute. Eyes of the other 6 rabbits were not washed. Readings of ocular lesions for all animals were made at 1, 24, 48, 72 hours and 7 days after treatment. Sodium fluorescein was used to aid in revealing possible corneal injury.
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<b>Result</b>	: There was no pain response during instillation of the test material and no corneal or iridial irritation was seen during the study. Any irritation that occurred had cleared by 48 hours. The primary eye irritation scores for the first 48 hours of the study were as follows:
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<b>Period</b>	<b>Unwashed eyes</b>	<b>Washed eyes</b>
1 hour	2.7	2.0
24 hours	0.3	0
48 hours	0	0

<b>Reliability</b>	: (1) Valid without restriction
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(11)

<b>Species</b>	: Rabbit
<b>Concentration</b>	: Undiluted
<b>Dose</b>	: .1 ml
<b>GLP</b>	:
<b>Test substance</b>	: Various base oils

<b>Remark</b>	: CONCAWE summarized the data available on eye irritation for the lubricating oil base stocks. The data are shown in the following table.
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	<b>Irritation*</b>	<b>API report No.</b>
<b>Paraffinic distillates</b>		
Solvent dewaxed, light		

## 5. Toxicity

**Id** Lubricating Oil  
Basestocks  
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API 78-9 (64742-56-9)	Slight	29-33104
Solvent dewaxed, heavy		
API 78-10** (64742-56-0)	Non	29-33105
API 79-3 (64742-65-0)	Non	29-33067
API 79-4 (64742-65-0)	Non	29-33066
API 79-5 (64742-65-0)	Non	29-33068

### Naphthenic distillates

Solvent refined, light		
API 78-5 (64741-97-5)	Non	29-33106
Solvent refined, heavy		
API 79-1 (64741-96-4)	Non	29-33065
Hydrotreated, heavy		
API 83-15 (64742-52-5)	Slight	33-32639

### Other mineral oils

Paraffin oil**	Slight	Carpenter & Smyth
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\* NB Irritation described as slight, moderate or non-irritating

\*\* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information  
(2) (3) (4) (5) (6) (7) (8) (13) (68) (71)

## 5.3 SENSITIZATION

<b>Type</b>	: Buehler Test
<b>Species</b>	: Guinea pig
<b>Concentration</b>	: 1 <sup>st</sup> : Induction 25 % occlusive epicutaneous 2 <sup>nd</sup> : Challenge 1 % occlusive epicutaneous
<b>Number of animals</b>	: 10
<b>Vehicle</b>	: Paraffin oil
<b>Result</b>	: Not sensitizing
<b>Year</b>	: 1986
<b>GLP</b>	: Yes
<b>Test substance</b>	: Unrefined base oil, Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.
<b>Method</b>	: 0.4 ml of a 25% mixture of test material and paraffin oil was applied under an occlusive dressing to the shorn skin of 10 male and 10 female animals. 6 hours after application the dressings were removed and the skin wiped to remove residues of test material. The animals received one application each week for 3 weeks. The same application site was used each time. 2 weeks following the third application, a challenge dose (0.4 ml of a 1% mixture in paraffin oil) was applied in the same manner as the sensitizing doses. A previously untreated site was used for the challenge application. The application sites for sensitizing and challenge doses were read for erythema and edema 24 and 48 hours after patch removal. To assist in the reading of the response to the final challenge dose the test site was depilated 3 hours prior to reading by using a commercially available depilatory cream.

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<b>Result</b>	<p>Positive control (2,4-dinitrochlorobenzene at 0.3% in 80% aqueous ethanol), vehicle control and naive control groups were included in this study and the procedure for these was the same as for the test groups.</p> <p>: The criteria used to evaluate the responses are described in the report as follows: Determination of sensitization was based upon reactions to the challenge dose. Grades of 1 or greater in the test animals indicate evidence of sensitization, provided grades of less than 1 are seen in the naive controls. If grades of 1 or greater are noted in the naive control animals, then the reactions of test animals that exceed the most severe naive control reaction are considered sensitization reactions.</p> <p>Using these criteria, none of the test animals became sensitized following treatment with API 84-01. In contrast, all the positive control animals were sensitized by their treatment.</p>	
<b>Reliability</b>	: (1) Valid without restriction	(12)
<b>Type</b>	: Buehler Test	
<b>Species</b>	: Guinea pig	
<b>Concentration</b>	: 1 <sup>st</sup> . Induction 50 % occlusive epicutaneous 2 <sup>nd</sup> . Challenge 1 % occlusive epicutaneous 3 <sup>rd</sup> .	
<b>Number of animals</b>	: 10	
<b>Vehicle</b>	: Paraffin oil	
<b>Result</b>	: Not sensitizing	
<b>Year</b>	: 1986	
<b>GLP</b>	: Yes	
<b>Test substance</b>	: Highly refined Base oil, Sample API 83-12 [CAS64742-53-6] See section 1.1.1.	
<b>Method</b>	<p>: 0.4 ml of a 50% mixture of test material and paraffin oil was applied under an occlusive dressing to the shorn skin of 10 male and 10 female animals. 6 hours after application, the dressings were removed and the skin wiped to remove residues of test material. The animals received one application each week for 3 weeks. The same application site was used each time. 2 weeks following the third application, a challenge dose (0.4 ml of a 1% mixture in paraffin oil) was applied in the same manner as the sensitizing doses. A previously untreated site was used for the challenge application. The application sites for sensitizing and challenge doses were read for erythema and edema 24 and 48 hours after patch removal. To assist in the reading of the response to the final challenge dose the test site was depilated 3 hours prior to reading by using a commercially available depilatory cream.</p> <p>Positive control (2,4-dinitrochlorobenzene at 0.3% in 80% aqueous ethanol), vehicle control and naive control groups were included in this study and the procedure for these was the same as for the test groups.</p>	

## 5. Toxicity

**Id** Lubricating Oil  
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### Result

: The criteria used to evaluate the responses are described in the report as follows:

Determination of sensitization was based upon reactions to the challenge dose. Grades of 1 or greater in the test animals indicate evidence of sensitization, provided grades of less than 1 are seen in the naive controls. If grades of 1 or greater are noted in the naive control animals, then the reactions of test animals that exceed the most severe naive control reaction are considered sensitization reactions.

One animal had a score of 0.5 after challenge with API 83-12. In contrast, all the positive control animals were sensitized by their treatment. The sample of API 83-12 was therefore non sensitizing.

### Reliability

: (1) Valid without restriction

(11)

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**Type** : Buehler Test  
**Species** : Guinea pig  
**Test substance** : Various base oils

**Remark** : CONCAWE summarized the data available on skin sensitization for the lubricating oil basestocks. The methods and criteria used were the same as those described in the previous two robust summaries. The data are shown in the following table.

### Sensitization API Report

#### **Paraffinic distillates**

Solvent dewaxed, light			
API 78-9	64742-56-9	Non	29-33104
Solvent dewaxed, heavy			
API 78-10*	64742-56-0	Non	29-33105
API 79-3	64742-65-0	Non	29-33067
API 79-4	64742-65-0	Non	29-33066
API 79-5	64742-65-0	Non	29-33068

#### **Naphthenic distillates**

Solvent refined, light			
API 78-5	64741-97-5	Non	29-33106
Solvent refined, heavy			
API 79-1	64741-96-4	Non	29-33065
Hydrotreated, heavy			
API 83-15	64742-52-5	Non	33-32639

\* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information  
(2) (3) (4) (5) (6) (7) (8) (13) (71)

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### 5.4 REPEATED DOSE TOXICITY

**Type** : Sub-acute  
**Species** : Rat  
**Sex** : Male/female  
**Strain** : No data  
**Route of admin.** : Inhalation  
**Exposure period** : 14 days  
**Frequency of treatm.** : Six hours per day  
**Control group** : Yes  
**NOAEL** : > 50 mg/m<sup>3</sup>  
**Year** : 1989  
**GLP** : No data  
**Test substance** : Two samples of highly refined, solvent extracted dewaxed paraffinic base oil

**Method** : Groups of 5 male and 5 female rats were exposed to oil mists generated from two highly refined oils. Exposures were by inhalation six hours each day for a total of 10 days. The two oils were examined in separate experiments. The dose groups were:

Group	Mean actual concentration (mg/m <sup>3</sup> )	Mass median particle size (µm)
Controls	Air only	N/A
Oil 1	55	1.5
	507	1.9
	1507	2.2
Oil 2	Air only	N/A
	50	1.5
	513	1.9
	1480	2.2

**Remark** : No further experimental details are provided.  
A further two week inhalation study in rats has been reported for two mineral oil mists (Skyberg et al, 1990). The results largely confirm those described by Whitman et al. with respect to liver weight changes and histological observations in respiratory tissues.

**Result** : Oil 1  
All treated animals survived to study termination. The fur of all animals was saturated with test material and the amount of material present was clearly related to the exposure concentration. Alopecia and scabs subsequently formed in the highest 2 dose groups. Animals in the highest dose group were relatively unresponsive to auditory stimulation. Decreased body weight associated with a decrease in food consumption was recorded for the high dose animals.

Biologically significant increases in relative lung and liver weights were observed in the males and females in the

## 5. Toxicity

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high dose group but only in the mid dose females.  
An increase in white cell counts and the percentage of neutrophils and a decrease in the percentage lymphocytes was observed in the high dose groups only.  
There were no treatment related histopathological changes in the lowest 2 dose groups. Animals in the highest dose group exhibited the same changes as those observed in the nasoturbinates and lungs of animals exposed to oil 2 (See below)

### Oil 2

Clinical observations were the same as for those animals exposed to Oil 1, except that there was no scabbing and no treatment related alterations in food consumption.  
There was a biologically significant increase in absolute and relative lung weights in males and females at the high dose and in females only at the mid dose.  
Apart from elevated liver alanine and aspartate transaminase levels in the high dose females there were no other treatment related effects.

Histological effects considered to be treatment related consisted of an increase in the amount of perivascular and peribronchial lymphoid proliferations and an increase in mixed inflammatory cell infiltrations in the terminal bronchioles and alveolar ducts of the highest two dose groups. Increases in the appearance of focal hyperplasia and squamous cell metaplasia of the anterior nasal mucosa associated with inflammatory cell infiltration were observed in the two highest dose groups. These changes were indicative of mild irritation of the nasal mucosa.

### Reliability

The NOELs for the two oils were  $>50 \text{ mg/m}^3$   
: (4) Not assignable  
The information is taken from a poster presentation and a reliability score cannot be assigned.  
However, the data are supportive of the other study on inhalation of oil mist reported by Dalbey et al.

(106) (111)

**Type** : Sub-acute  
**Species** : Rat  
**Sex** : Male/female  
**Strain** : Sprague-Dawley  
**Route of admin.** : Inhalation  
**Exposure period** : 4 weeks  
**Frequency of treatm.** : 6 hours/day, 5 days/week  
**Doses** : 50, 220 &  $1000 \text{ mg/m}^3$   
**Control group** : Yes, concurrent no treatment  
**Year** : 1991  
**GLP** : No data  
**Test substance** : 3 base oils

### Method

: Groups of 10 male and 10 female rats were exposed to aerosol concentrations of the three test materials at nominal concentrations of 0, 50, 220 and  $1000 \text{ mg/m}^3$ .  
Exposures were for 6 hours each day, 5 days each week for 4 weeks. Total number of exposures for each of the three test

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materials was: 17, 18 and 20 days for SRO, WTO and HBO respectively. Food and water were available ad libitum during non-exposure periods. Clinical observations were made prior to each exposure and body weights were recorded weekly. Animals were sacrificed within 72 hours of the last exposure after being fasted overnight. Blood samples were taken for a range of hematology and serum chemical parameters. The hematological parameters consisted of: Total white and red cells, hemoglobin, hematocrit, MCV, MCH, and MCHC. A differential white cell count was also conducted. The following chemical parameters were measured: Alanine transferase, albumin, albumin/globulin ratio, alkaline phosphatase, aspartate aminotransferase, total bilirubin, calcium, chloride, cholesterol, creatinine, globulin, glucose, iron, lactate dehydrogenase, inorganic phosphorus, potassium, total protein, sodium, triglycerides, urea nitrogen and uric acid. All animals were necropsied and the following organs were weighed: gonads, heart, kidneys, liver, spleen, and thymus. The right middle lobe of the lung was weighed immediately after removal and again after drying. A range of tissues were fixed and prepared for a histopathological examination. Sperm from the cauda epididymis of each control and high dose male was examined for an assessment of sperm morphology.

### Result

: Chamber concentrations  
The aerosol concentrations were comparable among the three base stocks. Qualitatively, the aerosols were virtually identical to each liquid base oil. The actual concentrations for each of the aerosols was as follows:

	<b>Nominal</b>	<b>Actual</b>
SRO	0	0
	50	50 ±10
	220	210 ±10
	1000	1020 ±60
WTO	0	0
	50	50 ±10
	220	210 ±10
	1000	980 ±20
HBO	0	0
	50	47 ±2
	220	220 ±10
	1000	980 ±50

The mass median diameter was well under 2µm for each base stock

### Toxicity assessment

Apart from occasional loose stool there were no treatment related clinical observations and body weights were

## 5. Toxicity

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unaffected by exposure.

No treatment related effects were found in any of the hematological or clinical chemical parameters that were measured.

The percent sperm with aberrant morphology, including breakage, was unaffected by exposure to any of the three base oils.

There were no treatment-related observations at necropsy and, with the exception of the lungs, there were no significant changes in organ weights.

Wet and dry lung weights increased in a dose-related manner.

The percentage increases in wet weight are shown in the following table.

For simplicity increases are shown to nearest whole numbers

Sex	Dose (mg/m <sup>3</sup> )	% Increase in wet lung weight		
		SRO	WTO	HBO
Female	50	3	8	2
	210	4	23*	34*
	1000	38*	64*	36*
Male	50	5	-	1
	210	12*	1	6
	1000	33*	31*	32*

\* denotes differences that are statistically significant (P<0.05) compared to controls.

The ratios of wet to dry lung weights were significantly increased for both sexes at the highest dose concentration for all three base oils.

Morphologically, treatment related changes were only observed in the lungs and tracheobronchial lymph nodes. Foamy macrophages with numerous vacuoles of varying size were present in the alveolar spaces of the lungs of many of the exposed animals. The histological changes are summarized in the following table.

No. of animals in each group with a given histopathological change

Tissue/change	Dose group		
	50	210	1000
<b>SRO</b>			
Lung			
1-2 Foamy macrophages (FM)	20	20	20
3-6 FM	0	0	20
Thickened alveolar wall	0	0	0
FM in alveolar interstitium	0	0	0
Mild alveolar PMN infiltrate	0	5	20
Lymph nodes			
Anterior mediastinal			
Macrophage accumulation	NE	NE	9
Tracheobronchial			

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FM accumulation	NE	NE	19
Macrophage accumulation	NE	NE	0

### WTO

Lung			
1-2 Foamy macrophages (FM)	20	20	20
3-6 FM	0	0	20
Thickened alveolar wall	0	0	0
FM in alveolar interstitium	0	0	0
Mild alveolar PMN infiltrate	0	0	19
Lymph nodes			
Anterior mediastinal			
Macrophage accumulation	NE	NE	0
Tracheobronchial			
FM accumulation	NE	NE	0
Macrophage accumulation	NE	NE	19

### HBO

Lung			
1-2 Foamy macrophages (FM)	0	16	16
3-6 FM	0	0	16
Thickened alveolar wall	0	0	16
FM in alveolar interstitium	0	0	16
Mild alveolar PMN infiltrate	0	0	0
Lymph nodes			
Anterior mediastinal			
Macrophage accumulation	NE	NE	2
Tracheobronchial			
FM accumulation	NE	NE	0
Macrophage accumulation	NE	NE	3

NE denotes Not Evaluated

Only 16 animals in the HBO high dose group were examined

### Test substance

: Three materials were examined in this study. The properties of the materials designated SRO, WTO and HBO are shown in the following table.

SRO Solvent refined oil CAS # 64742-70-7

WTO White oil CAS # 8042-47-5. [Prepared by severely hydrotreating a dewaxed feedstock and then acid washing with fuming sulfuric acid.]

HBO Hydrotreated base oil CAS #64742-54-7 [Severely hydrotreated heavy paraffinic oil produced by treatment of the vacuum distillate with hydrogen at high temperature and pressure (hydrotreating and hydrocracking)].

	SRO	WTO	HBO
Viscosity at 100 °F	106	85	161
Pour point (°F)	20	15	-5
API Gravity	32.8	34.6	33.6
Furfural (ppm)	1	0	<1
Nitrogen (ppm)	44	-	8
Sulfur (wt.%)	0.20	-	<0.06
Composition (wt.%)			

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Paraffins	36	60	29.7
Mononaphthenes	22.3	-	30.6
Polynaphthenes	22.3	-	37.3
Monoaromatics	12.8	0	0.6
Diaromatics	3.3	0	0.8
Polyaromatics	1.4	0	1.0
Unidentified aromatics	0.4	0	0
Aromatic sulfur types	1.1	0	0

**Reliability** : (2) Valid with restrictions  
It is not clear whether the study was carried out according to GLP, but otherwise it was a well conducted and well reported study.

(73)

**Type** :  
**Species** : Rabbit  
**Sex** : Male/female  
**Strain** : New Zealand white  
**Route of admin.** : Dermal  
**Exposure period** : 6 hours each day  
**Frequency of treatm.** : 3 times each week for a total of 12 applications  
**Doses** : 200, 1000 and 2000 mg/kg  
**Control group** : Yes  
**Year** : 1986  
**GLP** : Yes  
**Test substance** : Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.

**Method** : Undiluted API 84-01 was applied at doses of 200, 1000 and 2000 mg/kg/day to the shorn dorsal skin of groups of five male and five female rabbits. The test material was applied to the skin 3 times each week for 4 weeks (12 applications total). The applied material was covered with an occlusive dressing for 6 hours, which was then removed and the skin was wiped with a dry gauze to remove any residual material. A group of five rabbits of each sex served as sham controls. The test skin site of each animal was examined and scored for irritation prior to each application of test material. Mortality and moribundity checks were performed twice daily and body weights were recorded weekly. At termination, blood samples were taken for a range of hematological and clinical chemical measurements. Urine samples were also collected and frozen for possible future examination. A complete gross necropsy was performed on all animals. Major organs were weighed and tissues were processed for subsequent histopathological examination.

**Result** : Three animals died during the study but these were not dose-related and were, therefore, considered unrelated to treatment. Sporadic clinical signs were also unrelated to treatment.  
In the high dose group, body weight gains were affected by treatment. In the females, there was a group net loss in weight whereas in the males the gains were significantly less than controls. These effects were largely due to effects on growth rate during the first week of the study. A mean irritation index was calculated for each group each day and also for each treatment group overall. The value

was determined from Draize scores for erythema and edema for each animal. The mean irritation scores for each group were:

Group	Irritation score
Control (male)	0
Control (female)	0
200 mg/kg (male)	0.5
200 mg/kg (female)	0.4
1000 mg/kg (male)	1.7
1000 mg/kg (female)	2.0
2000 mg/kg (male)	3.1
2000 mg/kg (female)	3.2

There were no statistical differences between treated and control groups for any of the hematological determinations. These were: Total red blood cells, total white blood cells, hemoglobin concentration and hematocrit %.

The clinical chemical data for the treated and control males was similar. In the females, there was a reduced BUN and an increased SGPT for the low dose females. Since no other differences were noted and that values were within normal limits the effects were not considered to be toxicologically significant. The clinical chemical measurements consisted of: glucose, BUN, SGOT, SGPT, ALP and total protein.

The following absolute and relative organ weight differences (compared to controls) were recorded.

#### 2000 mg/kg

	Males	Females
Relative liver wt.	Increased	Increased
Relative kidney wt.	Increased	Increased
Relative pituitary wt.	Increased	
Relative left testis wt.	Decreased	
Relative brain wt.		Increased

#### 1000 mg/kg

Abs. Rt. kidney wt.	Decreased
Abs. Heart wt.	Decreased

None of the organ weight differences were considered treatment-related. The higher than control relative organ weights were considered as a function of the reduced body weights in the affected animals.

The only findings at gross necropsy were confined to the treated skin. These consisted of dry, scaly, rough, and/or reddened skin and thickened dermis. These findings were noted throughout the treatment groups. There were no treatment-related gross necropsy findings in the internal organs.

Microscopic pathology findings were also largely confined to the skin. Slight to moderate proliferative changes of the

## 5. Toxicity

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skin were present in all of the male and female rabbits in the highest dose group.

The testes of one of the five males in the high dose group had bilateral diffuse tubular hypoplasia accompanied by aspermatogenesis and hypoplasia of the epididymis. These changes were considered to represent immature testes. Similar changes were not seen in the other animals in this dose group.

**Reliability** : (1) Valid without restriction

(10)

**Type** :  
**Species** : Rabbit  
**Sex** : Male/female  
**Strain** : New Zealand white  
**Route of admin.** : Dermal  
**Exposure period** : 6 hours each day  
**Frequency of treatm.** : 3 times each week for a total of 12 applications  
**Doses** : 200, 1000 and 2000 mg/kg  
**Control group** : Yes  
**Year** : 1986  
**GLP** : Yes  
**Test substance** : Highly refined Base oil, Sample API 83-12 [CAS64742-53-6]  
See section 1.1.1.

**Method** : Undiluted API 83-12 was applied at doses of 200, 1000 and 2000 mg/kg/day to the shorn dorsal skin of groups of five male and five female rabbits. The test material was applied to the skin 3 times each week for 4 weeks (12 applications total). The applied material was covered with an occlusive dressing for 6 hours, which was then removed and the skin was wiped with a dry gauze to remove any residual material. A group of five rabbits of each sex served as sham controls. The test skin site of each animal was examined and scored for irritation prior to each application of test material. Mortality and moribundity checks were performed twice daily and body weights were recorded weekly. At termination, blood samples were taken for a range of hematological and clinical chemical measurements. Urine samples were also collected and frozen for possible future examination.

A complete gross necropsy was performed on all animals. Major organs were weighed and tissues were processed for subsequent histopathological examination.

**Result** : No deaths occurred during the study. Skin irritation occurred to varying degrees in all animals treated with API 83-12. There was moderate irritation in the high dose males and females. In the mid dose group moderate irritation occurred in the females and slight irritation in the males. In the low dose group minimal irritation occurred in both sexes. The overall mean irritation scores were:

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<b>Dose level (mg/kg)</b>	<b>Males</b>	<b>Females</b>
Control 0	0	0
200	0.1	0.4
1000	2.0	2.2
2000	2.6	3.1

Soft stool was also observed in several animals but this also occurred in a control male was not considered to be dose related. All high dose females appeared thin and this was considered to be treatment related. Body weight gains were reduced in the high dose males and females and in the mid dose females when compared to their respective controls. Overall weight changes (kg) are shown in the following table

<b>Dose level (mg/kg)</b>	<b>Males</b>	<b>Females</b>
Control 0	+0.5	+0.3
200	+0.3	+0.4
1000	+0.3	0.0*
2000	+0.1*	-0.2*

\* statistically significant ( $p \leq 0.05$ )

Clinical chemical and hematological values were considered to be unaffected by treatment. A low value for white cell count in the low dose female group was considered incidental since the value was within a normal range and was not a dose-related effect.

Although there were some organ weight differences, they were considered incidental to treatment. The exception was for the absolute testis weights, which were lower in the high dose males and the relative weights of the right testis which were also lower than controls.

At gross necropsy, findings for the skin consisted of dry, scaly, rough, fissured, crusted and/or thickened skin. This was a common finding in all treatment groups.

Histopathological examination revealed slight to moderate proliferative changes in the skin in all rabbits in the high dose group. These changes were accompanied by an increased granulopoiesis of the bone marrow. The testes of 3 of the 5 males in the high dose group had bilateral diffuse tubular hypoplasia accompanied by aspermatogenesis and atrophy of the accessory sex organs. There were no changes observed in either the testes or epididymes of the male rabbits in the mid or low dose groups. No other treatment-related histopathological changes were recorded.

**Reliability** : (1) Valid without restriction

(9)

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**Species** : Rabbit  
**Route of admin.** : Dermal  
**Test substance** : Various Base oils

**Remark** : Data on repeated dose dermal studies in rabbits have been summarized elsewhere (CONCAWE 1997).  
The attached tabulated summary of information is taken from the CONCAWE publication.

**Attached document** : See Attachment 4. Summary of Repeated Dermal Studies with Base Oils  
(2) (3) (4) (5) (6) (7) (8) (14) (71) (108)

**Species** : Rat  
**Sex** : Male/female  
**Strain** : Fischer 344  
**Route of admin.** : Oral feed  
**Exposure period** : 90 days  
**Frequency of treatm.** : Continuous in food  
**Doses** : 0.002, 0.02, 0.2 & 2.0% in the diet  
**Control group** : Yes  
**Method** : OECD Guide-line 408 "Subchronic Oral Toxicity - Rodent: 90-day Study"  
**Year** : 1992  
**GLP** : Yes  
**Test substance** : White oil

**Method** : Three related, but separate studies were carried out at the same time on 6 different food grade white oils and 3 food grade waxes.  
Only the information on the oils is included here. The information on waxes is included in the Waxes and Related Materials HPV Test Plan.

In the main study, groups of 20 male and 20 female rats were fed diets containing one of 6 different white oils at dietary concentrations of 0.002, 0.02, 0.2 and 2.0% for 90 days. Further groups of 60 male and 60 females were fed untreated control diet. Additionally groups of 20 rats of each sex were fed diets containing 2.0% coconut oil.

The second study was a reversibility study. Groups of 10 rats of each sex were fed diets for 90 days containing one of the 6 different oils at the 2.0% level or coconut oil at 2%. These animals were then fed control diet for 28 days following the 90-days treatment. Groups of 30 rats of each sex served as controls for this reversibility study.

A third study was designed to determine tissue levels of hydrocarbons. In this study, 5 rats of each sex were fed diets containing one of the 6 oils or coconut oil at the 2.0% dietary level for 90 days. Extra groups of rats (5 of each sex) were fed control diet or coconut oil or one of the six oils for 90 days followed by exposure to control diet only for a further 28 days.

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### Remark

In all three studies, animals were monitored for weight, food intakes and clinical condition throughout. An ophthalmic examination was performed prior to treatment and prior to necropsy on the animals in the main study and those for the study of reversibility.

A full necropsy was performed on the main and reversibility study animals and a full range of hematological parameters were measured on blood samples taken from the animals. Clinical chemical measurements were also made on serum separated from the blood samples. A selection of organs was weighed and a range of tissues retained for subsequent histopathological examination. All tissues from the high dose group and control groups were examined by light microscopy. Additionally the liver, lymph nodes, spleen, kidney, small intestine and lung were examined from all the intermediate dose groups.

Mineral hydrocarbon levels were measured in a limited number of tissues in those animals designated for tissue level determinations.

: While only one report (three studies) is described here, numerous repeat dose studies on white oils destined for use in foods have been conducted and reported in the open literature.

### Result

Recent studies with a low molecular weight white oil have demonstrated that the F 344 rat is more sensitive in its response to mineral hydrocarbons than the Sprague Dawley rat (Firriolo et al). Indeed other studies on white oils with Sprague Dawley rats (McKee et al) and beagle dogs (Bird et al) have also not resulted in any reported effects.

: The six oils tested had average molecular weights ranging from 320 to 510. The effects observed in the study were inversely related to the oil's molecular weight. Thus the oil with the lowest molecular weight caused the most severe effects and at lower dose levels than the higher molecular weight materials. For simplicity, only the results of the highest and lowest molecular weight oils are summarized below. Furthermore, the results of the reversibility study are not given in detail here.

In general, there was evidence of reversibility of the effects but reversibility was not complete for all of the parameters measured.

P 100 H (Average molecular weight 510)

There were no treatment-related clinical signs, nor was there an effect on body weight. Food consumption was increased in the males of the highest dose group but this was less than 10% greater than for the controls. Ophthalmic examination did not reveal any effects. Organ weights, hematology and clinical chemistry were unaffected except for a 10% increase in ASAT in the males in the highest dose group.

There were no treatment-related findings at necropsy and the histological examination did not reveal any treatment-related effects.

A small amount of mineral hydrocarbon was found in the

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livers of the male rats in the highest dose group.

N 10 A (Average molecular weight 320)

There were no treatment-related clinical signs, nor was there an effect on body weight. Food consumption was increased in the males of the highest dose group but this was less than 10% greater than for the controls. Ophthalmic examination did not reveal any effects.

### Organ weights

Increases in organ weights are as shown below, other organ weights were unaffected.

Organ	Increases (%) at Dietary concentration			
	Males		Females	
	0.2%	2.0%	0.2%	2.0%
Kidney (abs.)	4	6		5
(rel.)		7		7
Liver (abs)	8	11	6	21
(rel.)	6	12	8	23
Spleen (abs.)				17
(rel.)		5		19
MLN* (abs.)		224		220
(rel.)		224		226

\* Mesenteric Lymph Node weights only determined for the 2% dose group in the reversal group of animals and not for the main study animals.

### Hematology

In the males in the highest dose group there were increases in Neutrophils (41%), monocytes (28%) and basophils (200%)  
In the females, changes occurred in the 2% and 0.2% dose groups. These were as follows:

	Change (% + or -) at dose level	
	0.2%	2%
RBC	- 2	- 3
Hemoglobin	- 2	- 3
WBC		+ 23
Differential WBC		
Neutrophils		+ 75
Monocytes		+ 51
Eosinophils		+ 38

### Clinical chemistry

In the males there was a reduction in Alkaline phosphatase of 8 and 2% in the 2 and 0.2% dose groups respectively. Changes in clinical chemical parameters in the females were as follows:

	Change (% + or -) at dose level	
	0.2%	2%
ALKP	- 12	- 13
ASAT		+ 12
Gamma GT		+ 91
A/G ratio		- 8

### Histopathology

#### Liver

Liver lesions comprised microgranuloma or granuloma, the distinction between being purely related to size. Lesions were classified as microgranuloma if the average diameter was less than 25% of the average hepatic lobule. The histological features of the two were similar and consisted of collections of macrophages, some with necrotic cells surrounded by inflammatory cells and variable fibrosis.

No lesions were observed in the males whereas granulomas were seen in the females in the highest dose group. In females in the recovery group 28 days after cessation of exposure, the incidence was unchanged but the severity of the lesions had decreased.

#### Mesenteric Lymph node

The lymph node lesions comprised focal collections of macrophages, often in the cortical region. The macrophages were lightly vacuolated, giving a slightly foamy appearance to their cytoplasm. Some macrophages had a yellowish-brown pigmentation of varied intensity. The focal collections of macrophages were classified as histiocytosis and were scored as minimal, mild, moderate or marked based on size and abundance. The foci of histiocytosis were not homogeneously distributed; they were often restricted to one node or even to part of one node.

Histiocytosis was also found in control rats but was generally restricted to isolated foci and was always classified as minimal.

Compared to controls, in males histiocytosis increased down to the 0.2% dose group. In the females, histiocytosis was also observed in the 0.02% dose group.

In the reversibility group the severity and incidence was reduced after being fed control diet for 28 days.

#### Ileum and jejunum

There was a significant increase in vacuolation of the

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lamina propria in the high dose female group.

In summary, the NOELs and LOELs for the six oils that were tested are as follows.

	Oil	LOEL	NOAEL
		(histiocytosis) Dietary concentration	
<b>Test substance</b>	N10A	0.02%	
	N15H	0.002%	
	P15H	0.02%	
	N70A	0.02%	
	N70H	0.02%	
	P100H	-	2.0%
	: Six white oils examined in this study were characterized. Only the average molecular weight and viscosity at 100 °C are shown below:		

Sample	Viscosity (cSt)	Average Molecular Weight
N10(A)	3.08	320
N15(H)	3.45	330
P15(H)	3.52	350
N70(A)	7.88	410
N70(H)	7.65	420
P100(H)	11	510

**Reliability** : (1) Valid without restriction

(20) (86) (93)

### 5.5 GENETIC TOXICITY 'IN VITRO'

**Type** : Modified Ames Assay  
**System of testing** : Salmonella typhimurium strain TA98  
**Metabolic activation** : With  
**Year** : 1984  
**Test substance** : Various base oils  
The baseoils tested had PAC contents ranging from 0.2 to 12%. It is generally recognized that those base oils with PAC contents less than 3% are highly refined oils whereas those with greater values are considered to be poorly refined. This distinction was recognized and used by the EU in its classification of base oils. (Ref 70, 75)

**Method** : The method differed from the standard pre- incubation Ames assay in the following respects.

A DMSO extract of the test materials was tested in the assay.

The S9 fraction was obtained from Araclor-induced hamsters.

An eightfold concentration of S-9 was used in the assays.

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Twofold concentration of cofactor NADP was used.

The DMSO extracts were tested over a range of concentrations that permitted the construction of a dose-response curve.

A Mutagenicity Index was determined for each assay. This was the tangent to the dose response curve at zero dose.

An assay was judged to be positive if the Mutagenicity Index was greater than 1.0

### Result

: Roy describes the mutagenicity results for a range of petroleum-derived materials, 28 of which were lubricating oil base stocks.  
A Mutagenicity Index (MI) was determined for each test material and this was compared to the PAC content and to a carcinogenicity index that had also been determined for each material.  
The results were as follows.

Sample	MI*	%PAC**	%T***	%T/LP****
5	0.9	0.9	0	4.17
6	0	0.3	0	0
7	0.9	0.9	2	4.17
8	0	0.6	0	0
9	0	0.3	0	0
10	0	0.7	2	3.28
12	2.4	3.1	4	5.93
13	9.1	10	26	71
14	0	0.7	2	3.45
15	0	0.2	0	0
16	3.9	3.7	6	1.6
17	4	3.1	8	14.3
18	3.6	4.9	10	21.7
19	6.5	5.2	10	23.4
20	9.2	7.7	40	138
26	0	0.5	2	2
27	0	0.5	2	3.92
28	0	0.3	0	0
29	0	0.6	0	0
30	0	0.6	0	0
32	10	12	54	154
33	5.9	7.8	42	73.7
34	4.1	4.1	50	104
35	1.2	1.2	4	6.25
36	2.1	1.5	18	38.3
37	0	0.7	2	2.13
38	4.5	4.6	24	46.2
39	0	1.2	0	0

\* MI denotes Mutagenicity index.

\*\* %PAC is weight % of 3-7 ring PNAs in the oil.

\*\*\* %T is the percentage of mice with tumors in skin carcinogenicity studies reported elsewhere.

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	****	%T/LP is the percentage of mice with tumors multiplied by the reciprocal of the latency period. The author describes this as a carcinogenic potency index.
Conclusion	:	Base stocks with no or low concentrations of PACs have low Mutagenicity indices. Also, those oils that were negative in the modified Ames assay (MI < 1.0) were not carcinogenic in mouse skin painting studies.
Reliability	:	Those oils which were positive in the modified Ames assay had significant levels of PACs and were carcinogenic. (1) Valid without restriction (22) (24) (98)
Type	:	Modified Ames Assay
System of testing	:	Salmonella typhimurium strain TA98
Metabolic activation	:	With
Result	:	Negative
GLP	:	No data
Test substance	:	Residual base oils
Method	:	<p>The test substance (Canthus 1000, a deasphalted, dewaxed residual oil) was diluted 1:5 in DMSO and then shaken, centrifuged and separated into 2 fractions. Two assays were conducted for the test substance: an initial assay and a repeat assay. All plates were evaluated following approximately two days of incubation. Test volumes of 5, 10, 15, 20, 30, 40, 50 and 60 µl/plate were prepared by dilution of the DMSO fraction in DMSO and dosed at a final volume of 60 µl. The volumes were added to each plate with metabolic activation (hamster S9) and tester strain TA98 following the procedures outlined by Blackburn et al., (1986) and the methods described in the American Society for Testing Materials (ASTM) document, "The Standard Test Method for Determining Carcinogenic Potential of Virgin Base Oils in Metalworking Fluids". The same test volumes were used in the repeat assay.</p> <p>A positive control and vehicle control were tested concurrently.</p> <p>Linear regression analysis (ASTM: E 1687-95) was performed on the test substances which caused an increase in the mean number of revertant colonies when compared to the vehicle control. Only data from the linear portion of the dose response curve was used to generate the mutagenicity index (MI). If the increase in revertant colonies was not statistically significant or if there was no increase in the mean number of revertant colonies, then the MI value was considered to be 0 (revertants/µl DMSO extract).</p> <p>Data from both the initial and repeat assays on the test material (Canthus 1000) were pooled to generate a single linear MI value. With this procedure, an MI value &gt; 1.0 (revertants/µl DMSO extract) is considered indicative of a potential dermal carcinogen in mice (Blackburn et al, 1996). Conversely, a test substance is considered unlikely to be carcinogenic in mouse skin when the MI value is &lt; 1.0 (revertants/µl DMSO extract).</p>

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**Result** : The MI for Canthus 1000 was determined to be 0.2 revertants/μl DMSO extract.  
Thus, under the conditions of this study, Canthus 1000 was considered negative for inducing frameshift mutations in Salmonella typhimurium.

**Reliability** : (4) Not assignable  
This summary is based on a summary of the results of a study. It is not possible, therefore to assign a reliability to this study. The data however are useful, together with other similar data to demonstrate that residual base oils are not mutagenic in a modified Ames assay.

(18) (22) (23) (85)

**Type** : Modified Ames Assay  
**System of testing** : Salmonella typhimurium strain TA98  
**Metabolic activation** : With  
**Result** : Negative

**Remark** : Summaries are available on Modified Ames assays that have been carried out on 3 additional residual base oils and a vacuum residuum.  
The results and references to the studies are shown below.  
Under the conditions of this study, the test materials were considered negative for inducing frameshift mutations in Salmonella typhimurium.

Material	Mutagenicity Index (MI)	Reference
Vacuum residuum	0.8	Petrolabs (1998)
Bright stock	0.11	Petrolabs (2000)
150 SUS Bright stock	0	EMBSI
150 Solvent		
Bright stock	0	EMBSI

**Reliability** : (4) Not assignable  
This summary is based on a summary of the results of a study. It is not possible, therefore, to assign a reliability to this study. The data, however, are useful, together with other similar data, to demonstrate that residual base oils are not mutagenic in a modified Ames assay.

(74) (96) (97)

### 5.6 GENETIC TOXICITY 'IN VIVO'

**Type** : Cytogenetic assay  
**Species** : Rat  
**Sex** : Male/female  
**Strain** : Sprague-Dawley  
**Route of admin.** : gavage  
**Exposure period** : 5 days  
**Doses** : Ranged from 500 to 2000 and 500 to 5000 mg/kg

**Method** : A full description of the method is not given in the publication.  
The publication includes the following information:

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### Result

The rat bone marrow cytogenetics assay was performed after administration of each sample of the test materials to 5-10 males and 5-10 female Sprague Dawley rats per dose level. In gavage studies, the samples were dissolved in corn oil or saline and administered at a dosage of 5 ml/kg. Acute studies and 5-day subchronic tests were performed in the early stages of the work, but in subsequent assays only the subchronic test was performed. A positive control chemical, triethylenemelamine (TEM) was tested concurrently.

: The results tabulated in the publication are as follows:

Sample	Dose (mg/kg)	No. animals	No. cells	Aberrant cells (%)
<b>Paraffinic oils</b>				
64 SUS	Corn oil	8	400	4.3
	500	10	500	3.8
	1000	9	450	2
	2000	10	500	2.8
133 SUS	Corn oil	10	500	3
	500	8	400	1.3
	1000	10	500	2
	2000	10	500	1
331 SUS	Corn oil	10	500	4
	500	9	450	3.8
	1000	8	450	5.6
	2000	10	500	7*
485 SUS	Corn oil	7	350	4
	500	9	450	4.9
	1000	8	400	4.3
	2000	7	350	5.7
990 SUS	Corn oil	8	400	1
	500	6	300	1.3
	1000	9	450	1.6
	2000	8	400	2.5
<b>Naphthenic oils</b>				
80 SUS	Saline	19	950	0.4
	500	17	850	0.4
	1670	19	950	0.6
	5000	20	1000	0.4
2000 SUS	Saline	19	950	0.7
	500	18	874	0.7
	1670	18	900	1.6
	5000	15	750	0.4
TEM	0.4-1.0			24.2-41.8*

\* denotes significant by Wilcoxon rank test

### Test substance

: Two naphthenic and 5 paraffinic base stocks were tested. The characteristics of the samples tested are as follows:

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Sample	Initial boiling point (° F)	Aromatics (%)	PNAs (%)
<b>Paraffinic oils</b>			
SUS at 100 °F			
64	536	10.2	0.4
133	639	13.8	0.7
331	636	28.1	3.0
485	572	27.8	4.1
990	515	31.9	4.8
<b>Naphthenic oils</b>			
SUS at 100 °F			
80	470	23.8	0.8
2000	611	37.7	4.5

### Reliability

: (4) Not assignable

The publication presents a summary of a program of work carried out for the API.

Since raw data are not presented in the publication, a reliability rating cannot be assigned.

Nevertheless, the information is useful in demonstrating the lack of in-vivo genotoxic activity of the base oils containing low levels of PACs.

(69)

### 5.7 CARCINOGENICITY

**Species** : Mouse  
**Sex** : Male/female  
**Route of admin.** : Dermal  
**Exposure period** : Up to 84 weeks  
**Frequency of treatm.** : Once or twice weekly  
**Doses** : Various  
**Control group** : Yes, concurrent no treatment  
**Test substance** : Distillate base oils

**Remark** : Numerous skin carcinogenicity studies have been carried out on lubricating base oils derived from distillates. Data from these studies have been summarized and reviewed elsewhere.

No single study is summarized here but the general conclusions that may be drawn from the numerous studies are:

Highly refined base oils are not skin carcinogens.

Poorly refined or unrefined base oils are skin carcinogens.

A good correlation exists between skin carcinogenic potential and level of DMSO extractables and polycyclic aromatic compounds present in the base oil.

The degree of carcinogenicity is dependent on the level of polycyclic aromatic compounds present in the base oil.

When applied repeatedly to the skin, carcinogenic base oils are associated only with skin tumors and not with an increase in systemic tumors.

There is a good correlation between skin carcinogenicity and Mutagenicity Index as determined in a modified Ames assay.

(21) (24) (70) (71) (89) (98)

**Species** : Mouse  
**Sex** : Female  
**Strain** : CF No. 1  
**Route of admin.** : Dermal  
**Exposure period** : 18 months  
**Frequency of treatm.** : Three times weekly  
**Doses** : 0.1ml/application  
**Result** : Negative  
**Control group** : Yes  
**Year** : 1991  
**GLP** : No data  
**Test substance** : Residual base oils

**Method** : 0.01 ml of undiluted test material was spread three times weekly over the shorn dorsal skin of a group of 50 female CF No.1 mice. A further two groups of 5 female mice underwent

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similar treatment and were killed after 22 or 52 weeks.

The appearance and development (or regression) of superficial tissue masses was recorded weekly throughout the study, to enable calculation of the latency period of those subsequently diagnosed as being tumors.

A positive control group of 50 female mice was treated with an oil (N1) that had been shown in previous studies to be a skin carcinogen. The mice in the positive control group received the oil once a week for 22 weeks and then once every 14 days for a total of 78 weeks.

A group of 50 untreated female mice served as negative controls.

### Result

: Minimal evidence of skin irritation was visible following treatment with the test materials.  
No treatment-related effects were observed on clinical condition, body weight gain or mortality (NB survival rates for treated animals are not included in the report).  
Changes recorded at post mortem were considered normal.  
Histopathological examination of the skin of the treated mice provided no evidence of skin irritation and no tumors of epidermal origin were observed.

No cutaneous tumors were recorded in the group of untreated control mice (52% of animals survived to termination after 2 years)

The positive control group had skin reactions at the treatment site which included redness, scabbing, cracking and flaking; histopathological examination confirmed the presence of chronic inflammation (acanthosis, hyperkeratosis, ulcers, parakeratosis and scabs). In addition, skin reactions, principally at the margins of the treatment site were frequently recorded and were particularly seen during the first 22 weeks of treatment. These reactions typically included abrasions and ulceration. The severity of the lesions was such that many animals were killed on humane grounds; only 24% of animals survived to 78 weeks.

Histopathological examination of the skin revealed that over 78 weeks, 23 mice in the positive control group had 56 tumors of epidermal origin, of which 39 were benign (papillomas and keratoacanthomas) and 17 were malignant (squamous cell carcinomas and one single malignant basal cell tumor). The mean latency period was 37 weeks.

### Test substance

: The test substance was described as:  
"A non-solvent refined, deasphalted, dewaxed residual paraffinic lubricant base oil"

<u>Characteristic</u>	<u>Value</u>
Kinematic viscosity	
at 40 °C	1024 cSt
at 60 °C	266.6 cSt
at 100 °C	42.52 cSt
Density at 15 °C	0.9280 kg/l
Pour point	+3 °C

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Flash point (COC)	315 ° C
Refractive index	1.5142
Color (D1500)	8.0
Molecular weight (D2502)	660
Sulfur	1.7% wt
Aniline point	105.0 deg C
Volatiles 3 hrs at 13 ° C	0.10%
Neutralization value	0.02 mg KOH/g
Viscosity gravity constant (D2140)	0.846
Refractivity intercept	1.0598
Molecular type (D2007)	
Saturates	46.3% wt
Aromatics	45.6% wt
Polars	8.0% wt
Carbon type (D2140)	
CA	15%
CN	19%
CP	66%

Total and individual PCA concentrations on completion of study

Individual PCA	mg/kg
Fluoranthene	0.2
Pyrene	0.9
Benz(a)anthracene	0.3
Chrysene/triphenylene	2.5
Benzo(a)fluoranthene	1.0
Benzo(e)pyrene	1.6
Benzo(a)pyrene	0.1
Perylene	0.1
Dibenz(a,j)anthracene	<0.1
Dibenz(a,h)anthracene	<0.1
Indeno(1,2,3-cd)pyrene	<0.1
Benzo(ghi)perylene	<0.1
Total PCA content (BP3 method)	7.0% wt

### Reliability

: (4) Not assignable  
This report is a summary report and as a consequence does not provide full experimental details, but does provide sufficient information for a conclusion to be made on the skin carcinogenic potential of a non-solvent refined residual paraffinic base oil.

(91)

**Species** : Mouse  
**Sex** : Male  
**Strain** : C3H  
**Route of admin.** : Dermal  
**Frequency of treatm.** : 3 times weekly  
**Post exposure period** :  
**Doses** : 25 µl per application  
**Result** : Negative  
**Control group** : Yes  
**GLP** : No data  
**Test substance** : Canthus 210 a Deasphalted, dewaxed, residual oil

**Method** : The summary states that the design of the study was similar to other conventional skin painting studies in mice.

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The test material was applied undiluted in 25 µl aliquots to the clipped dorsal back regions of 50 male C3H/HeJ mice, three times weekly. At each treatment period, the dorsal skin was examined for the presence of papillomas/carcinomas, and each animal was also examined daily for any clinical signs of ill health. Treatment continued for 24 months. A complete necropsy was conducted at the time of sacrifice. In this study, Primol 185, a medicinal grade white mineral oil was applied undiluted and served as the negative control. Heavy Clarified Oil (HCO) was applied as a 10% solution in Primol 185, and served as the positive control.

**Result** : None of the animals treated with the test material or the negative control material developed skin tumors, or any other tumors considered treatment-related, over the course of the study. The positive control material, 10% HCO, responded as anticipated, producing squamous cell carcinomas in 47 of 50 treated animals.

**Reliability** : (4) Not assignable  
The information given is based on a summary of the study and hence it is not possible to assign reliability to the study. Nevertheless, the data provide useful information on the carcinogenic potential of residual base oils.

(76)

**Species** : Rat  
**Sex** : Male/female  
**Strain** : Fischer 344  
**Route of admin.** : Oral feed  
**Exposure period** : 2 years  
**Frequency of treatm.** : Daily in the diet  
**Doses** : 60, 120, 240 and 1200 mg/kg/day  
**Result** : Negative  
**Control group** : Yes  
**Method** : OECD Guide-line 453 "Combined Chronic Toxicity/Carcinogenicity Studies"  
**Year** : 2001  
**GLP** : Yes  
**Test substance** : White oil

**Remark** : This study is a study that was conducted according to OECD guidelines. It is not described in full in this summary since it is not one of the SIDS base set requirements.

**Result** : Survival was unaffected by exposure to the test material. There were no treatment related clinical signs, or any effects on body weight, food consumption, food conversion efficiency or ophthalmology. Furthermore, there was no treatment related effects on the hematological, serum chemistry or urinalysis parameters that were measured. At gross necropsy, there were no treatment-related gross observations and there were no treatment-related neoplastic changes.

**Test substance** : The test material is a 70 cSt white oil with an average molecular weight of 485.

**Reliability** : (1) Valid without restriction

(84)

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**Species** : Rat  
**Sex** : Male/female  
**Strain** : Fischer 344  
**Route of admin.** : Oral feed  
**Exposure period** : 104 weeks  
**Frequency of treatm.** : Continuous in the feed  
**Doses** : 2.5 and 5% in the diet  
**Result** : Negative  
**Control group** : Yes  
**Year** : 1997

**Result** : There were slight increases in body weights in both sexes of the 5% group (5% for males and 2.7% for females) at week 104. Food consumption was also increased in the 5% groups (11% for males and 8% for females total increase at week 104). However, no significant treatment-related differences between the control and treated groups were observed for clinical signs, mortality or hematological findings. In the 5% group, absolute liver and kidney weights were increased in males and absolute and relative submaxillary gland weight were reduced in females. Absolute and relative weights of heart and spleen were unaffected by treatment. The percentage increases/decreases in the 5% group were:

<u>Organ</u>	<u>Absolute</u>	<u>Relative</u>
<u>Female</u>		
Submaxillary gland	3% decrease	1.7% decrease
<u>Male</u>		
Liver	8.4% increase	not different
Kidney (R)	14.9% increase	not different
Kidney (L)	9.9% increase	not different

In the 5% male group, the increased absolute organ weights were attributed to the slight increases in body weights.

A variety of tumors developed in all groups, including the control group. However, all the neoplastic lesions were histologically similar to those known to occur spontaneously in F344 rats, and no statistically significant increase in the incidence of any tumor type was found for either sex in the treated groups.

Granulomatous inflammation in the mesenteric lymph nodes, considered to be a reaction to paraffin absorption, was observed with similar incidence and severity in both sexes of the 2.5 and 5% groups.

The authors concluded that under the present experimental conditions, the high dose, about 2000-200,000 times higher than the current temporary acceptable daily intake, did not have any carcinogenic potential in F344 rats. Furthermore, the granulomatous inflammation observed in the mesenteric lymph nodes was not associated with any development of

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**Test substance** : neoplastic lesions.  
The test material was composed of equal quantities of eight different commercially available liquid paraffins (highly refined white oils) obtained from eight member companies of the Japan Liquid Paraffin Industry.  
Each of the eight liquid paraffins complied with the requirements of the Japanese food additive and Japanese Pharmacopoeia standards. 5 of the component material had been derived from petroleum by acid treatment and the other eight had been derived by hydrotreatment.  
The physical properties of a sample of the composite test material were determined by CONCAWE and were as follows:

Viscosity at 40°C	0.871
Viscosity at 100 °C	8.68
Ratio of naphthenic/paraffinic hydrocarbon	35/65
Average molecular weight	475
Carbon No. at 5% boiling point	25

**Reliability** : (2) Valid with restrictions  
Although the experimental details are not provided here, the information is nevertheless useful in establishing the lack of carcinogenicity by the oral route.

(105)

### 5.8.1 TOXICITY TO FERTILITY

**Type** : One generation study  
**Species** : Rat  
**Sex** : Male/female  
**Strain** : Sprague-Dawley  
**Route of admin.** : Gavage  
**Frequency of treatm.** : Daily  
**Doses** : 1.15 mg/kg  
**Control group** : No  
**Method** : OECD Guideline 421, Reproductive/Developmental Toxicity screening test  
**Year** : 1995  
**GLP** : Yes  
**Test substance** : Chevron 100 neutral (refined) CAS 64742-54-7

**Method** : The method used was as described in OECD guideline 421.

The base oil was administered by gavage at a dose of 1.15 mg/kg (bw) to a group of 12 male and 12 female Sprague Dawley rats. Rats designated F0 animals were dosed for a minimum of 14 days prior to mating. Dosing was continued after mating until a total dosing period of 30 days had elapsed for males and until day 4 of lactation for females (39 days).  
The animals were observed twice daily for appearance, behavior, moribundity and mortality. Males and females were also observed during dosing and for one hour thereafter. Male F0 body weights were recorded weekly. Female F0 body weights were also recorded weekly until evidence of mating was observed and then on gestation days 0, 7, 14 and 20 and on lactation days 1 and 4. Food consumption was also

recorded for F0 both sexes.  
Animals were paired on a 1:1 basis. Positive evidence of mating was confirmed either by the presence of sperm in a vaginal smear or a vaginal plug. The day when evidence of mating was identified was termed Day 0 of gestation.

The following Fertility indices were calculated:

Female mating index  
Male mating index  
Female fertility index  
Male fertility index

All females were allowed to deliver their young naturally and rear them to post-natal day 4. Females were observed twice daily during the period of expected parturition for initiation and completion of parturition and for signs of dystocia. After parturition, litters were sexed and examined for evidence of gross malformations, numbers of stillborn and live pups.

Litters were examined daily and each pup received a detailed physical examination on days 1 and 4 of lactation. Any abnormalities were recorded.

The live litter size and viability index were calculated.

All surviving pups were necropsied on post-natal day 4.

A complete gross examination was made on all animals at necropsy.

Selected organs of parental animals were weighed and a wide range of tissues was fixed for subsequent histopathological examination.

**Result** : Only the results for the base oil control group are reported below.

There were no clinical findings and growth rates and food consumption values were normal.

Fertility indices and mating indices for males and females were both 100%.

At necropsy, there were no consistent findings and the animals were considered to be normal.

Organ weights and histopathology was considered normal.

**Reliability** : (2) Valid with restrictions  
The study was on an oil additive in base oil at two concentrations. The base oil alone was used as the control. Therefore, no control was available with which to compare the study control group. However, since all the recorded values were within normal limits, it could be concluded that the base oil was without effect.

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## 5. Toxicity

**Id** Lubricating Oil  
Basestocks  
**Date** March 24, 2003

**Type** : One generation study  
**Species** : Rat  
**Sex** : Male/female  
**Strain** : Sprague-Dawley  
**Route of admin.** : Gavage  
**Exposure period** : 13 weeks prior to mating  
**Frequency of treatm.** : 5 times weekly  
    **Male** : 13 weeks  
    **Female** : 13 weeks  
**Duration of test** : One generation after 13 weeks dosing  
**No. of generation studies** : 1  
**Doses** : 5 ml/kg  
**Control group** : No  
**Year** : 1987  
**GLP** : No data  
**Test substance** : White oil CAS 8012-95-1

**Method** : 72 female and 36 male Sprague-Dawley rats were given white oil at a dose of 5 ml/kg, 5 days a week for 13 weeks. After this time each of the males was housed with 2 females for 10 consecutive nights, or until mating was confirmed by the appearance of a copulatory plug or by the presence of sperm in a vaginal rinse.  
The mated females were maintained without further dosing through gestation and lactation to post-partum day 21. Detailed maternal physical examinations and body weight measurements were made on days 0, 7, 14 and 21 of gestation and on days 0, 4, 14 and 21 of lactation.  
All dams and surviving litters were sacrificed and grossly examined on day 21 of lactation. Each of the offspring was examined for external malformations. All pups were then sacrificed, necropsied and subjected to visceral organ and brain examination. Pups which died spontaneously were also necropsied unless this was precluded by cannibalism or autolysis.

**Remark** : White oil was used as solvent control in a study to determine the effects of two EDS coal liquids in a 13 week subchronic a single generation reproduction study. There were three dose groups and a control group for each test material in this study. The information in this robust summary relates only to the white oil control groups (one for each of the test materials) and NOT to the groups exposed to EDS coal liquids.

The CAS# for the material that was used in this study is not included in the Lubricating Base Stocks category. However, because white oils are so highly purified, toxicologically and compositionally they are all very similar. Therefore, the Testing Group thinks the results on CAS # 8012-95-1 are applicable to the highly refined base oils that are included in this category.

**Result** : The data for the two control groups are summarized below.

<u>Parameter</u>	<u>Control 1</u>	<u>Control 2</u>
Impregnation frequency	80.8%	80.9

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Gestation	22.6 days	22.6
Pups delivered	11.7	11.1
Live births	11.2	10.7
Survival at day 4	10.5	9.6
Survival at day 14	10.2	9.3
Survival at day 21	10.1	9.3

Offspring body weights		
Day 0 lactation	6.7	6.9
Day 4 lactation	9.3	9.9
Day 14 lactation	26.9	27.1
Day 21 lactation	43.2	46.7

No unusual behavior was reported during the gestation period for either of the control groups.

The general condition of offspring and dams was good through weaning.

Gross observations of pups and dams were generally unremarkable.

In one base oil group, 3 malformed pups were found in 2 litters. Two of the malformed pups had syndactyly and renal agenesis and one of these also exhibited agnathia. The third pup had a small eye.

In the other control group, four malformed pups were found in 4 litters. Two of the pups had tail abnormalities, one had a depression in the sternum and the fourth had a short snout.

The authors comment that a similar spectrum of malformations in Sprague-Dawley rats from the same supplier has been reported elsewhere. The authors also comment that this spectrum of malformations can occur spontaneously in the Sprague-Dawley rat and are not regarded as treatment-related.

### Reliability

: (2) Valid with restrictions  
Not all the raw data are presented in this publication. However, the data are useful in determining that white oils do not cause effects on reproduction after prior exposure for 13 weeks.

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## 5. Toxicity

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### 5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

**Species** : Rat  
**Sex** : Female  
**Strain** : Sprague-Dawley  
**Route of admin.** : Gavage  
**Exposure period** : Days 6 through 19 of gestation  
**Frequency of treatm.** : Daily  
**Year** : 1987  
**GLP** : No data  
**Test substance** : White oil CAS 8012-95-1

**Method** : Two groups of animals (50 and 25) were administered white oil by gavage at a dose of 5 ml/kg, every day during gestation days 6 to 19 inclusive. Food and water were available continuously. Animals were examined for viability and clinical effects twice daily. Body weights were recorded on days 0, 6, 10 and 20 of gestation. On day 20 of gestation, all animals were euthanized with methoxyfluorane and examined for gross changes. Each gravid uterus was removed and weighed. The number, location and viability of each fetus and the number of implant sites were recorded. Fetuses were removed, weighed and the crown-rump lengths measured. All live and dead fetuses that had not been resorbed were examined for external malformations. Approximately half of the fetuses from each litter were decapitated and the heads preserved for subsequent examination for abnormalities. The viscera were also examined for malformations under low power magnification. The remaining fetuses were stained with Alizarin red and subsequently examined for skeletal abnormalities. No organs, other than the uteri were weighed and no organs were examined histologically in this study.

**Remark** : White oil was used as the solvent control in two separate studies, one for each of two test materials. This summary only reports on the outcome of the animals in the two control groups.

The CAS# for the material that was used in this study is not included in the Lubricating Base Stocks category. However, because white oils are so highly purified, toxicologically and compositionally they are all very similar. Therefore, the Testing Group thinks the results on CAS # 8012-95-1 are applicable to the highly refined base oils that are included in this category.

**Result** : One animal died in the control group containing 50 animals and this was attributable to mis-dosing. Increases in body weight during the study were considered normal. These with other recorded parameters are summarized in the table below.

Day of gestation	Group 1 (25 rats)	Group 2 (50 rats)
Body weights (g)		
0	207.2	225.4

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6	227.5	248
10	235.9	259.3
15	260	284.3
20	329.1	351.9

Uterine wt	67.2	70.7
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Number of litters	25	49
Implants/litter	11.3	12.0
Resorptions/litter	0.06	0.47

Males		
No./litter	5.12	5.96
Crown-rump length (mm)	3.66	3.6
Wt. of fetuses	4.26	4.23

Females		
No./litter	5.6	5.61
Crown-rump length (mm)	3.61	3.52
Wt. of fetuses	4.02	4.07

In the control group containing 50 animals, 3 malformed fetuses were found in 3 litters; one had an extra lumbar vertebra, one had a discrete area of ossification in the area

of the junction of the frontal and nasal bones, one had moderately dilated lateral ventricles of the brain.

3 malformed fetuses were also found in 3 litters of the other control group. These were, a vertebral arterial canal of a cervical process fully ossified in 2 fetuses and angulated ribs in a third fetus.

The authors considered these malformations to be minor and that the findings were within the normal ranges for the strain of rat.

**Reliability** : (2) Valid with restrictions  
Although there were no untreated animals for comparison, the results were nevertheless, considered to be within normal limits. Consequently, the study is useful in providing evidence of the lack of developmental effects for white oil.

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### 5.11 ADDITIONAL REMARKS

**Type** : Correlation of toxicity with chemical components of refinery streams

**Remark** : Heavy vacuum gas oil is used as a starting material for base oil production. As such, it can be considered a "worst case" example of the unrefined/mildly refined base oil subcategory. Studies on this material are summarized below.

**Type** : 90-day study on Heavy vacuum gas oil

**Method** : Undiluted heavy vacuum gas oil was applied at doses of 0,

## 5. Toxicity

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Basestocks  
Date March 24, 2003

### Result

30, 125, 500 and 2000 mg/kg/day to the shorn skin of groups of ten male and ten female Sprague Dawley rats. The material was applied 5 days each week for 13 weeks. Collars were fitted to the animals to prevent oral ingestion. Body weights were recorded weekly throughout the study and clinical observations were made daily. Skin irritation was assessed weekly. At 5 and 13 weeks blood samples were taken for hematological and clinical chemical analyses. At the end of the study (13 weeks) all surviving animals were sacrificed and a gross necropsy examination was performed. 20 tissues were preserved for subsequent histopathological examination.

: Two males and one female in the high dose group died during the study. The male deaths were considered to be compound related but the female death was considered incidental. Growth rates of males and females in the highest dose group were reduced compared to controls. At 13 weeks the males weighed 20% less and the females 15% less than controls. At 2000 mg/kg/day males and females had reduced erythrocytes and reduced platelets at 5 and 13 weeks. Similar effects were also found in the 500 mg/kg/day females.

Clinical chemical changes in males and females at 2000 mg/kg/day consisted of:

- twofold increase in sorbitol dehydrogenase
- twofold increase in cholesterol
- 50% reduction in uric acid

In addition in females at 500 mg/kg/day, glucose was reduced and in the 500 mg/kg males cholesterol was increased.

At gross necropsy, relative thymus weights were reduced in the 500 (by 25%) and 2000 mg/kg/day (by 50%) animals of both sexes. Relative liver weights were also increased at 500 and 2000 mg/kg/day for both sexes.

Histological examination revealed decreased erythropoiesis and fibrosis of the bone marrow in the 2000 mg/kg/day males. There was a reduction in thymic lymphocytes in the 2000 mg/kg/day groups (marked for males and moderate for females) and a slight reduction in the 500 mg/kg/day groups for both sexes.

No effects were found on either sperm morphology or in the results of the urinalysis.

### Reliability

The NOEL for both males and females was found to be 125 mg/kg/day.

: (2) Valid with restrictions  
The report evaluated was incomplete but nevertheless was sufficient to identify the relevant effects of exposure to the test material.

(94)

### Type

: Developmental toxicity screen on Heavy vacuum gas oil

### Method

: Groups of 10 presumed-pregnant rats were distributed into the

## 5. Toxicity

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following groups:

Group	Dose level (mg/kg/day)	Gestation days of administration
1	0 (remote control)	0-19
2	0 (proximate control)	0-19
3	30	0-19
4	125	0-19
5	500	0-19
6	1000	0-19
7*	500 (bioavailability)	10-12

\* Group size was 5 at start but increased to 8 after study initiation.

The test material was applied daily to the shorn dorsal skin at the dose levels shown above and for the duration indicated. The rats were fitted with collars to prevent oral ingestion of the applied material.

Since it was believed that inhalation of test material could be a confounding factor a second group of controls (remote controls) were housed in an area in which they could not inhale gasoil that had been applied to other animals.

Observations were made daily for clinical signs and body weights and food consumption were recorded regularly throughout the study.

Each female was sacrificed on day 20 of presumed gestation and the thoracic and abdominal cavities were examined grossly.

The thymus and liver were removed from each animal and weighed and then preserved in formalin but not examined further.

The uterus and ovaries were removed and examined grossly.

The number of corpora lutea per ovary for each rat was recorded. The ovaries of non-pregnant females were examined and then discarded. Uterus weights were also determined.

The uterine contents of each pregnant rat were exposed and a record made of the number and location of all implantations.

At necropsy, blood samples were taken from all the animals and a range of clinical chemical measurements were made.

Fetuses were examined and half were preserved for examination of soft tissue abnormalities, the remainder being differentially stained for skeletal examination.

### Result

: Parental animals.

There were no clinical signs attributable to exposure to HVGO other than in the highest dose group in which 2 rats had a red vaginal discharge, one animal was pale in color and six had decreased stool. The latter observation was probably associated with a smaller food consumption in this group. Although food consumption was generally also less than controls in the 500 mg/kg/day group there was no associated body weight decrease. At doses in excess of 125 mg/kg/day there was a decrease in

## 5. Toxicity

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mean body weights which reflected the decreased litter sizes for this group.

The only dose-related finding at gross necropsy was a pale appearance of lungs in a few animals. 4 animals were affected at the highest dose and only one in the 500 mg/kg/day group.

Mean thymus weights of animals in the highest dose group were approximately half those of the control groups. Although absolute liver weights were unaffected by exposure to HVGO, mean relative liver weights were increased (approximately 15%) in groups exposed to doses greater than 125 mg/kg/day.

Observations of Dams at Caesarean section.

Parameters with treatment-related effects are shown below.

	Dose group (mg/kg/day)					
	0(R)	0(P)	30	125	500	1000
Pregnant females	9	10	10	8	10	9
Dams with viable fetuses	9	10	10	8	10	6
Dams with all resorptions	0	0	0	0	0	3
Mean litter size of viable fetuses	13.9	14	13.8	14.4	10	5.8
Resorptions						
Mean	1.1	0.6	1.1	1.1	5.6	9.9
% Dams with resorptions	56	50	70	63	100	100

Parameters unaffected were:

- No. premature births
- Female mortality
- No. corpora lutea
- No. implantation sites
- Pre-implantation losses
- Viable male fetuses
- Viable female fetuses
- No. dead fetuses

Fetal evaluations

fetal body weights were significantly reduced in fetuses exposed in utero to HVGO at doses in excess of 125 mg/kg/day.

Although there were differences between control and treated crown-rump lengths they were not statistically significant.

At the time of external examination, malformations were observed in one fetus in the 1000 mg/kg/day group. The fetus was edematous and pale in color. Both hindpaws were malformed; the digits were reduced in size with a subcutaneous hematoma located at the distal most aspect of each of the digits.

Malformations of the vertebral column were restricted to the

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**Test substance**  
**Reliability**

500 mg/kg/day group.  
Although a variety of skeletal malformations were observed in treated and control groups the degree of aberrant development in control fetuses was not as severe as in the HVGO-exposed groups.  
Visceral malformations were restricted to two fetuses in the 500 mg/kg/day group. One fetus had microphthalmia and the other fetus had a diaphragmatic hernia which displaced the heart from the left to right hand side.  
: Heavy vacuum gasoil CAS 64741-57-7  
: (2) Valid with restrictions  
The report evaluated was incomplete but nevertheless was sufficient to identify the relevant effects of exposure to the test material.

(95)

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## Attachments

**Id** Lubricating Oil  
Basestocks  
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### Attachment 1. Physico-chemical properties for selected lubricating oil basestocks





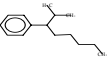




Base oil description	<u>Kinematic viscosity</u> *		Flash Point (°C)	Pour Point (°C)	Density (kg/l)	Average Molecular Weight
	at 40°C (mm <sup>2</sup> /s)	at 100°C (mm <sup>2</sup> /s)				
	ASTM D445	ASTM D445	ASTM D93	ASTM D97	ISO 12185	ASTM D2502
<b>Distillate oils</b>						
White mineral oil (8042-47-5)	27.3	5.0	217	-15	0.86	400
<b>Residual oils</b>						
Solvent-dewaxed (64742-62-7)	1300	50	285	-6	0.95	700

\*Kinematic viscosity is often expressed in Centistokes (cSt). It should be noted that 1 cSt = 1mm<sup>2</sup>/second.

## Attachments

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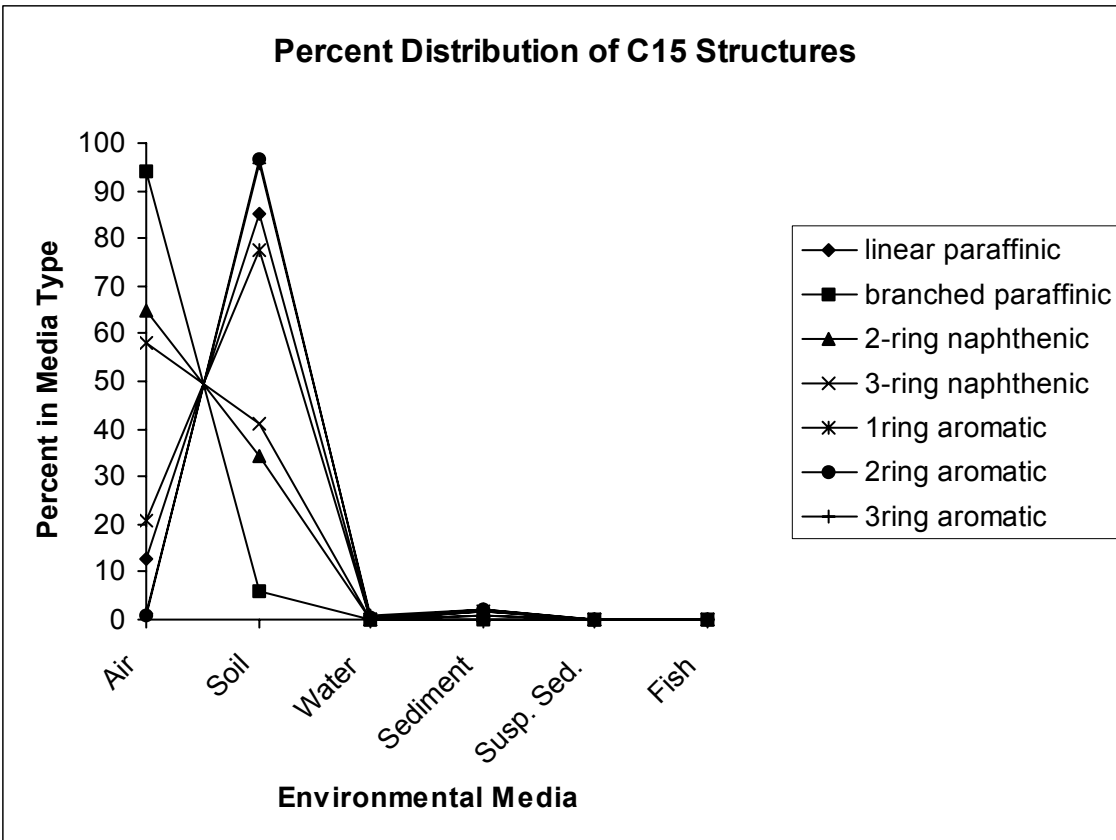
### Attachment 2. EQC Modeling Results of the Distribution Between Environmental Compartments

Structure		Percent Distribution - EQC Model					
		Air	Soil	Water	Sediment	Susp. Sed.	Fish
C15 linear paraffin		1.3E+01	8.5E+01	1.9E-03	1.9E+00	5.9E-02	4.8E-03
C15 branched paraffin		9.4E+01	5.8E+00	2.8E-04	1.3E-01	4.1E-03	3.3E-04
C15 2-ring naphthene		6.5E+01	3.4E+01	1.4E-02	7.6E-01	2.4E-02	1.9E-03
C15 3-ring naphthene		5.8E+01	4.1E+01	1.1E-01	9.1E-01	2.9E-02	2.3E-03
C15 1ring aromatic		2.1E+01	7.8E+01	4.2E-02	1.7E+00	5.4E-02	4.4E-03
C15 2ring aromatic		8.6E-01	9.7E+01	2.3E-01	2.1E+00	6.7E-02	5.5E-03
C15 2ring aromatic		4.4E-01	9.7E+01	1.4E-01	2.2E+00	6.8E-02	5.5E-03
C15 3ring aromatic		1.2E+00	9.6E+01	9.2E-01	2.1E+00	6.6E-02	5.4E-03
C15 3ring aromatic		1.5E+00	9.5E+01	8.8E-01	2.1E+00	6.6E-02	5.4E-03

## Attachments

Id Lubricating Oil  
Basestocks  
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### Attachment 3. Plot of the EQC Modeling Results of the Distribution Between Environmental Compartments



## Attachments

**Id** Lubricating Oil  
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**Date** March 24, 2003

### Attachment 4. Summary of Repeated Dermal Studies with Base Oils

Material	Duration	Dose (mg/kg)	Effects on skin	Systemic effects	API Report No.
<b>Paraffinic distillates</b>					
Unrefined API 84-01	28 days 3 doses per week	2000	Moderate irritation Proliferative changes	Marginal body weight decrease	33-31642
		1000	Slight irritation	None observed	
		200	Minimal irritation	None observed	
Solvent dewaxed, light API 78-9	21 days 4h/day 3 days/week	5000	Acanthosis, parakeratosis Chronic dermal inflammation	None observed	29-33065
Solvent dewaxed, heavy API 78-10*	"	5000	Acanthosis, parakeratosis Chronic dermal inflammation	None observed	29-33105
79-3	"	5000	None	None observed	29-33067
79-4	"	5000	None	None observed	29-33066
79-5	"	5000	None	None observed	29-33068
5 Paraffinic base oils	28 days 5 days per week	1000	Minor irritation	None observed	Trimmer et al, 1989
<b>Naphthenic distillates</b>					
Solvent refined, light API 78-5	"	5000	Acanthosis, parakeratosis Chronic dermal inflammation	None observed	29-33106
API 79-1	"	5000	None	None observed	29-33065
Hydrotreated, light API 83-12	28 days 3 doses per week	2000	Moderate irritation	Reduced testis weight	33-30499
		1000	Males: slight irritation Females: moderate irritation	None observed	
		200	Minimal irritation	None observed	
Hydrotreated, heavy API 83-15	28 days 3 doses per week	2000	Slight irritation hyperplasia	Elevated SGOT & SGPT, decreased body weight. Subacute hepatitis. Increased relative liver weight in females	35-32430
		1000	Slight irritation	Elevated SGOT & SGPT	
		200	Minimal irritation	None observed	

\* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information

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F003 5.3

F004 1  
F005 1  
F006 16-02-2003  
F007 19-11-2002  
EOR  
F001 40  
F002 1  
F003 5.3  
F004 2  
F005 2  
F006 16-02-2003  
F007 31-12-2002  
EOR  
F001 40  
F002 1  
F003 5.3  
F004 3  
F005 3  
F006 16-02-2003  
F007 13-02-2003  
EOR  
F001 40  
F002 1  
F003 5.4  
F004 2  
F005 2  
F006 16-02-2003  
F007 31-12-2002  
EOR  
F001 40  
F002 1  
F003 5.4  
F004 3  
F005 3  
F006 16-02-2003  
F007 16-09-2010  
EOR  
F001 40  
F002 1  
F003 5.4  
F004 4  
F005 4  
F006 16-02-2003  
F007 13-02-2003  
EOR  
F001 40  
F002 1  
F003 5.4  
F004 5  
F005 5  
F006 16-02-2003  
F007 19-11-2002  
EOR  
F001 40  
F002 1  
F003 5.4  
F004 7

F005 7  
F006 16-02-2003  
F007 31-12-2002  
EOR  
F001 40  
F002 1  
F003 5.4  
F004 8  
F005 8  
F006 16-02-2003  
F007 12-10-2002  
EOR  
F001 40  
F002 1  
F003 5.5  
F004 1  
F005 1  
F006 16-02-2003  
F007 10-02-2003  
EOR  
F001 40  
F002 1  
F003 5.5  
F004 2  
F005 2  
F006 16-02-2003  
F007 12-09-2010  
EOR  
F001 40  
F002 1  
F003 5.5  
F004 3  
F005 3  
F006 16-02-2003  
F007 12-09-2010  
EOR  
F001 40  
F002 1  
F003 5.6  
F004 1  
F005 1  
F006 16-02-2003  
F007 05-09-2002  
EOR  
F001 40  
F002 1  
F003 5.7  
F004 2  
F005 2  
F006 16-02-2003  
F007 12-09-2010  
EOR  
F001 40  
F002 1  
F003 5.7  
F004 4  
F005 4

F006 16-02-2003  
F007 05-09-2002  
EOR  
F001 40  
F002 1  
F003 5.7  
F004 5  
F005 5  
F006 16-02-2003  
F007 12-09-2010  
EOR  
F001 40  
F002 1  
F003 5.7  
F004 6  
F005 6  
F006 16-02-2003  
F007 12-09-2010  
EOR  
F001 40  
F002 1  
F003 5.7  
F004 7  
F005 7  
F006 16-02-2003  
F007 06-09-2002  
EOR  
F001 40  
F002 1  
F003 5.8.1  
F004 1  
F005 1  
F006 16-02-2003  
F007 12-09-2010  
EOR  
F001 40  
F002 1  
F003 5.8.1  
F004 2  
F005 2  
F006 16-02-2003  
F007 13-02-2003  
EOR  
F001 40  
F002 1  
F003 5.8.2  
F004 1  
F005 1  
F006 16-02-2003  
F007 13-02-2003  
EOR  
F001 40  
F002 1  
F003 5.9  
F004 1  
F005 1  
F006 16-02-2003

F007 05-09-2002  
EOB  
C  
B051 DS\_COMPONENT\_TAB  
F001 40  
F002 0  
F003 Lubricating oil basestocks  
F012 Y  
F010 16-02-2003  
F004 12031538  
F005 16-02-2003  
F006 12031538  
F007 16-02-2003  
F008 Lubricating oil basestocks  
F009 A35-01  
EOR  
F001 40  
F002 1  
F003 Baseoils  
F012 Y  
F010 16-02-2003  
F004 12031538  
F005 24-07-2001  
F006 12031538  
F007 24-07-2001  
F008 Baseoils  
F009 A35-01  
EOB  
C  
B115 GI\_COMPANY\_TAB  
F001 40  
F002 1  
F003 17-09-2010  
F004 IUC4  
F020 A36-003  
EOB  
C  
B101 GI\_GENERAL\_INFORM\_TAB  
F001 40  
F002 1  
F003 24-03-2003  
F004 IUC4  
F010 A04-06  
F011 A19-02  
EOB  
C  
B109 GI\_EXPO\_LIMIT\_TAB  
F001 40  
F002 1  
F003 09-09-2002  
F004 IUC4  
F007 A17-07  
F008 5  
F009 A16-03  
F010 10  
F011 A16-03  
EOB

C  
 B126 GI\_ADD\_REVIEWS\_TAB  
 F001 40  
 F002 1  
 F003 23-09-2001  
 F004 IUC31  
 F007 IARC reviewed, in 1984, the carcinogenicity information on lubricating  
 \* base oils and the outcome of their review was published in a Monograph.  
 EOR  
 F001 40  
 F002 3  
 F003 09-08-2001  
 F004 IUC31  
 F007 Bingham reviewed the literature for information on the carcinogenic  
 \* potential of petroleum hydrocarbons. This review contained information on  
 \* base oils.  
 EOR  
 F001 40  
 F002 4  
 F003 26-08-2002  
 F004 IUC4  
 F007 CONCAWE demonstrated that it was possible to distinguish between  
 \* carcinogenic and non-carcinogenic base oils on the basis of the level of  
 \* DMSO extractables. This approach was subsequently adopted in the EU for  
 \* classification purposes.  
 EOR  
 F001 40  
 F002 5  
 F003 26-08-2002  
 F004 IUC4  
 F007 The EU Scientific Committee for Food (SCF) and the WHO Joint Expert  
 \* Committee on Food Additives (JECFA) have reviewed the available data on  
 \* the toxicology of mineral hydrocarbons for food uses.  
 EOR  
 F001 40  
 F002 6  
 F003 11-10-2002  
 F004 IUC4  
 F007 The WHO published an Environmental Health Criteria document which  
 \* included summarized information on lubricating base oil stocks  
 EOB  
 C  
 B201 PC\_MELTING\_TAB  
 F001 40  
 F002 1  
 F003 12-11-2002  
 F004 IUC4  
 F015 A36-003  
 F012 P01-03:ASTM D97  
 F014 A03-02  
 F020 A01-03:Lubricating Base Oils; distillate oils, residual oils, and white  
 \* oilsVarious  
 EOB  
 C  
 B202 PC\_BOILING\_TAB  
 F001 40  
 F002 1

F003 12-11-2002  
F004 IUC4  
F016 A36-003  
F013 P03-03:Calculated by: MPBPWIN V1.40 (EPIWIN V3.10; US EPA 2000)  
F015 A03-01  
F018 A01-03:American Society for Testing and Materials (ASTM). 2002. Standard  
\* Test Method for Pour Point of Petroleum Products (Rotational Method).  
\* ASTM D5985-02, Volume 05.01, ASTM, West Conshohocken, PA.  
EOB  
C  
B204 PC\_VAPOUR\_TAB  
F001 40  
F002 1  
F003 13-02-2003  
F004 IUC4  
F015 A36-002  
F011 25  
F012 P06-01  
F013 1991  
F014 A03-03  
F018 A01-03:CAS No. 64742-65-0, Distillates (petroleum), solvent-dewaxed,  
\* paraffinic  
EOB  
C  
B301 EN\_PHOTODEGRADATION\_TAB  
F001 40  
F002 1  
F003 06-09-2002  
F004 IUC4  
F045 A36-003  
F007 A01-03: CAS No.: Various; Unrefined and acid treated base oils.  
F009 F02-05: Calculations by EPIWIN V3.10; AOPWIN V1.90.  
F010 2001  
F043 A03-01  
EOB  
C  
B302 EN\_STABILITY\_IN\_WATER\_TAB  
F001 40  
F002 1  
F003 02-02-2002  
F004 IUC31  
F040 A36-002  
F039 A03-01  
EOB  
C  
B305 EN\_TRANSPORT\_TAB  
F001 40  
F002 2  
F003 23-12-2002  
F004 IUC4  
F011 A36-003  
F007 F20-04: Mathematical computer model  
F008 F22-01: Soil, air, water, suspended sediment and sediment for C15  
\* hydrocarbon structures  
F009 F21-01: Calculations by EQC V2.11  
F010 1999  
EOB

C  
 B308 EN\_BIODEGRADATION\_TAB  
 F001 40  
 F002 1  
 F003 06-09-2002  
 F004 IUC4  
 F047 A36-003  
 F048 1  
 F007 A01-03: CAS No. 64742-65-0; Distillates (petroleum), solvent-dewaxed  
 \* heavy paraffinic  
 F008 F25-01  
 F009 F26-03  
 F010 1986  
 F011 F27-0166: Microorganisms were obtained from Canterbury Sewage Works (UK)  
 \* and prepared according to the prescribed methods for this test.  
 F046 A03-03  
 F052 28  
 F053 F05-01  
 EOR  
 F001 40  
 F002 3  
 F003 09-09-2002  
 F004 IUC4  
 F047 A36-002  
 F048 2  
 F007 A01-03: CAS No. 64742-54-7; Distillates (petroleum), hydrotreated heavy  
 \* paraffinic  
 F008 F25-01  
 F009 F26-20  
 F010 1995  
 F011 F27-0139  
 F046 A03-03  
 F052 28  
 F053 F05-01  
 EOR  
 F001 40  
 F002 7  
 F003 09-09-2002  
 F004 IUC4  
 F047 A36-003  
 F048 3  
 F007 A01-03: CAS No. 64741-89-5; distillates (petroleum), solvent-refined,  
 \* light paraffinic  
 F008 F25-01  
 F009 F26-16  
 F010 1990  
 F011 F27-0139  
 F046 A03-03  
 F052 28  
 F053 F05-01  
 EOR  
 F001 40  
 F002 18  
 F003 11-09-2010  
 F004 IUC4  
 F047 A36-003  
 F048 4

F007 A01-03: CAS No. 64741-89-5; distillates (petroleum), solvent-refined,  
\* light paraffinic  
F008 F25-01  
F009 F26-25: CEC Method L-33-T-82 using test medium from ISO Standard 7827 and  
\* OECD 301A and 301E  
F010 1991  
F011 F27-0139  
F046 A03-03  
F052 21  
F053 F05-01  
EOR  
F001 40  
F002 31  
F003 16-02-2003  
F004 IUC4  
F048 5  
F007 A01-03: Various base oils  
F008 F25-01  
EOB  
C  
B401 EC\_FISHTOX\_TAB  
F001 40  
F002 1  
F003 17-09-2010  
F004 IUC4  
F033 A36-003  
F034 1  
F007 A01-03: CAS No. 64741-89-5; distillates (petroleum), solvent-refined,  
\* light paraffinic  
F008 E01-04  
F009 E02-0139  
F010 E03-03  
F011 1990  
F012 96  
F013 E04-02  
F014 E05-02  
F031 A03-03  
F032 A03-03  
F050 C47-002  
EOR  
F001 40  
F002 15  
F003 30-12-2002  
F004 IUC4  
F007 A01-03: Various base oils  
F010 E03-05: Acute toxicity tests  
EOB  
C  
B402 EC\_DAPHNIATOX\_TAB  
F001 40  
F002 1  
F003 11-09-2010  
F004 IUC4  
F032 A36-003  
F033 1  
F007 A01-03: CAS No. 64742-53-6 or 64741-97-5, Distillates (petroleum),  
\* hydrotreated or solvent-refined light naphthenic

F008 E06-0010  
F010 1988  
F011 48  
F012 E04-02  
F013 E05-02  
F030 A03-01  
F031 A03-01  
F042 E01-05  
EOB  
F001 40  
F002 2  
F003 11-09-2010  
F004 IUC4  
F032 A36-003  
F033 2  
F007 A01-03: CAS No. 64742-53-6 or 64741-97-5, Distillates (petroleum),  
\* hydrotreated or solvent-refined light naphthenic  
F008 E06-0020  
F010 1988  
F011 96  
F012 E04-02  
F013 E05-02  
F030 A03-01  
F031 A03-01  
F042 E01-04  
EOB  
C  
B403 EC\_ALGAETOX\_TAB  
F001 40  
F002 1  
F003 30-12-2002  
F004 IUC4  
F036 A36-003  
F037 1  
F007 A01-03: CAS No. 64741-88-4; distillates (petroleum), solvent-refined,  
\* heavy paraffinic  
F008 E08-0055  
F009 E09-03  
F010 1991  
F011 E10-02  
F012 96  
F013 E04-02  
F014 E05-02  
F034 A03-03  
F035 A03-03  
F054 C47-002  
EOB  
C  
B406 EC\_CHRONDAPHNIATOX\_TAB  
F001 40  
F002 1  
F003 09-09-2002  
F004 IUC4  
F030 A36-003  
F031 1  
F007 A01-03: CAS No. 64741-88-4; distillates (petroleum), solvent-refined,  
\* heavy paraffinic

F008 E06-0010  
F009 E16-01  
F010 1995  
F012 21  
F013 E18-01  
F014 E05-02  
F028 A03-03  
F029 A03-03  
EOR  
F001 40  
F002 12  
F003 13-02-2003  
F004 IUC4  
F008 E06-0010  
F012 21  
F013 E18-01  
F014 E05-02  
EOB  
C  
B501 TO\_ACUTE\_ORAL\_TAB  
F001 40  
F002 1  
F003 19-11-2002  
F004 IUC4  
F017 A36-002  
F018 1  
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section  
\* 1.1.1.  
F008 T01-03  
F009 T02-24  
F011 1986  
F012 A02-04  
F014 5000  
F015 T04-01  
F016 A03-03  
F019 T24-03  
F020 5  
F021 T52-003: Non - administered undiluted  
F022 T23-42  
EOR  
F001 40  
F002 2  
F003 31-12-2002  
F004 IUC4  
F017 A36-002  
F018 2  
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See  
\* section 1.1.1.  
F008 T01-03  
F009 T02-24  
F011 1986  
F012 A02-04  
F014 5000  
F015 T04-01  
F016 A03-03  
F019 T24-03  
F020 5

F021 T52-003: Non - administered undiluted  
F022 T23-42  
EOR  
F001 40  
F002 3  
F003 13-02-2003  
F004 IUC4  
F018 3  
F007 A01-03: Various Base oils  
F008 T01-03  
F009 T02-24  
EOB  
C  
B502 TO\_ACUTE\_INHAL\_TAB  
F001 40  
F002 1  
F003 31-12-2002  
F004 IUC4  
F019 A36-002  
F020 1  
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See  
\* section 1.1.1.  
F008 T05-03  
F009 T02-24  
F011 1987  
F012 A02-03  
F013 2.18  
F015 T07-01  
F016 4  
F017 T08-01  
F018 A03-03  
F021 T24-03  
F022 5  
F023 T52-003: Air  
F024 T23-42  
EOR  
F001 40  
F002 2  
F003 11-09-2010  
F004 IUC4  
F020 2  
F007 A01-03: Various Base oils  
F008 T05-03  
F009 T02-24  
EOB  
C  
B503 TO\_ACUTE\_DERMAL\_TAB  
F001 40  
F002 1  
F003 19-11-2002  
F004 IUC4  
F017 A36-002  
F018 1  
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section  
\* 1.1.1.  
F008 T01-03  
F009 T02-23

F011 1986  
F012 A02-04  
F014 2000  
F015 T04-01  
F016 A03-03  
F019 T24-03  
F020 4  
F021 T52-003: None applied undiluted  
F022 T23-31  
EOR  
F001 40  
F002 2  
F003 31-12-2002  
F004 IUC4  
F017 A36-002  
F018 2  
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See  
\* section 1.1.1.  
F008 T01-03  
F009 T02-23  
F011 1986  
F012 A02-04  
F014 2000  
F015 T04-01  
F016 A03-03  
F019 T24-03  
F020 2  
F021 T52-003: None - applied undiluted  
F022 T23-31  
EOR  
F001 40  
F002 3  
F003 13-02-2003  
F004 IUC4  
F018 3  
F007 A01-03: Various Base oils  
F008 T01-03  
F009 T02-23  
EOB  
C  
B505 TO\_SKIN\_IRRITATION\_TAB  
F001 40  
F002 1  
F003 31-12-2002  
F004 IUC4  
F014 A36-002  
F015 1  
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section  
\* 1.1.1.  
F008 T02-23  
F009 T14-02  
F010 1986  
F012 T46-05  
F013 A03-03  
F017 T49-001  
F018 T50-001  
F019 24

F020 T55-001  
F021 6  
F022 4.3  
F023 T52-003: None - undiluted  
EOR  
F001 40  
F002 2  
F003 31-12-2002  
F004 IUC4  
F014 A36-002  
F015 2  
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See  
\* section 1.1.1.  
F008 T02-23  
F009 T14-02  
F010 1986  
F012 T46-05  
F013 A03-03  
F017 T49-001  
F018 T50-001  
F019 24  
F020 T55-001  
F021 6  
F022 5.4  
F023 T52-003: None - undiluted  
EOR  
F001 40  
F002 3  
F003 13-02-2003  
F004 IUC4  
F015 3  
F007 A01-03: Various base oils  
F008 T02-23  
F017 T49-001  
F019 24  
F020 T55-001  
EOB  
C  
B506 TO\_EYE\_IRRITATION\_TAB  
F001 40  
F002 1  
F003 19-11-2002  
F004 IUC4  
F014 A36-002  
F015 1  
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section  
\* 1.1.1.  
F008 T02-23  
F009 T16-02  
F010 1986  
F013 A03-03  
F017 T49-001  
F018 .1  
F019 T56-001  
F022 9  
EOR  
F001 40

F002 2  
F003 31-12-2002  
F004 IUC4  
F014 A36-002  
F015 2  
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See  
\* section 1.1.1.  
F008 T02-23  
F009 T16-02  
F010 1986  
F013 A03-03  
F017 T49-001  
F018 .1  
F019 T56-001  
F022 9  
EOR  
F001 40  
F002 3  
F003 13-02-2003  
F004 IUC4  
F015 3  
F007 A01-03: Various base oils  
F008 T02-23  
F017 T49-001  
F018 .1  
F019 T56-001  
EOB  
C  
B507 TO\_SENSITIZATION\_TAB  
F001 40  
F002 1  
F003 19-11-2002  
F004 IUC4  
F015 A36-002  
F016 1  
F007 A01-03: Unrefined base other TS: Unrefined base oil Sample API 84-01 [CAS  
\* 64741-50-0] See section 1.1.1.  
F008 T18-01  
F009 T02-10  
F010 T20-03  
F011 1986  
F013 T21-02  
F014 A03-03  
F017 10  
F018 T53-001  
F019 25  
F020 T49-002  
F021 T54-002  
F022 T53-002  
F023 1  
F024 T49-002  
F025 T54-002  
F030 T52-003: Paraffin oil  
EOR  
F001 40  
F002 2  
F003 31-12-2002

F004 IUC4  
F015 A36-002  
F016 2  
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See  
\* section 1.1.1.  
F008 T18-01  
F009 T02-10  
F010 T20-03  
F011 1986  
F013 T21-02  
F014 A03-03  
F017 10  
F018 T53-001  
F019 50  
F020 T49-002  
F021 T54-002  
F022 T53-002  
F023 1  
F024 T49-002  
F025 T54-002  
F030 T52-003: Paraffin oil  
EOR  
F001 40  
F002 3  
F003 13-02-2003  
F004 IUC4  
F016 3  
F007 A01-03: Various base oils  
F008 T18-01  
F009 T02-10  
EOB  
C  
B508 TO\_REPEATED\_DOSE\_TAB  
F001 40  
F002 2  
F003 31-12-2002  
F004 IUC4  
F030 A36-002  
F031 4  
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See  
\* section 1.1.1.  
F008 T02-23  
F009 T23-31  
F010 T24-03  
F011 T25-01  
F012 T26-16  
F013 1986  
F014 6 hours each day  
F015 3 times each week for a total of 12 applications  
F017 200, 1000 and 2000 mg/kg  
F018 T27-07  
F029 A03-03  
EOR  
F001 40  
F002 3  
F003 16-09-2010  
F004 IUC4

F030 A36-002  
F031 6  
F007 A01-03: White oil  
F008 T02-24  
F009 T23-16  
F010 T24-03  
F011 T25-09  
F012 T26-10  
F013 1992  
F014 90 days  
F015 Continuous in food  
F017 0.002, 0.02, 0.2 & 2.0% in the diet  
F018 T27-07  
F029 A03-03  
EOR  
F001 40  
F002 4  
F003 13-02-2003  
F004 IUC4  
F031 5  
F007 A01-03: Various Base oils  
F008 T02-23  
F011 T25-01  
EOR  
F001 40  
F002 5  
F003 19-11-2002  
F004 IUC4  
F030 A36-002  
F031 3  
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section  
\* 1.1.1.  
F008 T02-23  
F009 T23-31  
F010 T24-03  
F011 T25-01  
F013 1986  
F014 6 hours each day  
F015 3 times each week for a total of 12 applications  
F017 200, 1000 and 2000 mg/kg  
F018 T27-07  
F029 A03-03  
EOR  
F001 40  
F002 7  
F003 31-12-2002  
F004 IUC4  
F030 A36-003  
F031 2  
F007 A01-03: 3 base oils  
F008 T02-24  
F009 T23-42  
F010 T24-03  
F011 T25-08  
F013 1991  
F014 4 weeks  
F015 6 hours/day, 5 days/week

F017 50, 220 & 1000 mg/m3  
F018 T27-04  
F029 A03-02  
F032 C07-001  
EOR  
F001 40  
F002 8  
F003 12-10-2002  
F004 IUC4  
F030 A36-005  
F031 1  
F007 A01-03: Two samples of highly refined, solvent extracted dewaxed  
\* paraffinic base oil  
F008 T02-24  
F009 T23-47  
F010 T24-03  
F011 T25-08  
F013 1989  
F014 14 days  
F015 Six hours per day  
F018 T27-07  
F019 A02-04  
F020 50  
F022 T28-07  
F029 A03-02  
F032 C07-001  
EOB  
C  
B509 TO\_GENETIC\_IN\_VITRO\_TAB  
F001 40  
F002 1  
F003 10-02-2003  
F004 IUC4  
F016 A36-002  
F017 1  
F007 A01-03: Various base oils  
F008 T30-19: Modified Ames Assay  
F010 1984  
F011 Salmonella typhimurium strain TA98  
F012 T32-02  
EOR  
F001 40  
F002 2  
F003 12-09-2010  
F004 IUC4  
F016 A36-005  
F017 2  
F007 A01-03: Residual base oils  
F008 T30-19: Modified Ames Assay  
F011 Salmonella typhimurium strain TA98  
F012 T32-02  
F013 T33-02  
F014 A03-02  
EOR  
F001 40  
F002 3  
F003 12-09-2010

F004 IUC4  
F016 A36-005  
F017 3  
F008 T30-19: Modified Ames Assay  
F011 Salmonella typhimurium strain TA98  
F012 T32-02  
F013 T33-02  
EOB  
C  
B510 TO\_GENETIC\_IN\_VIVO\_TAB  
F001 40  
F002 1  
F003 30-10-2001  
F004 IUC31  
F018 A36-005  
F008 T34-01  
F009 T02-24  
F010 T23-42  
F013 T24-03  
F014 T25-03  
F015 5 days  
F016 Ranged from 500 to 2000 and 500 to 5000 mg/kg  
EOB  
C  
B511 TO\_CARCIINOGENICITY\_TAB  
F001 40  
F002 2  
F003 12-09-2010  
F004 IUC4  
F021 1  
F007 A01-03: Distillate base oils  
F008 T02-18  
F010 T24-03  
F011 T38-01  
F014 Up to 84 weeks  
F015 once or twice weekly  
F017 various  
F018 T27-04  
EOR  
F001 40  
F002 4  
F003 26-08-2002  
F004 IUC4  
F020 A36-002  
F021 4  
F007 A01-03: White oil  
F008 T02-24  
F009 T23-16  
F010 T24-03  
F011 T38-10  
F012 T39-04  
F013 2001  
F014 2 years  
F015 Daily in the diet  
F017 60, 120, 240 and 1200 mg/kg/day  
F018 T27-07  
F019 A03-03

F022 T33-02  
EOR  
F001 40  
F002 5  
F003 12-09-2010  
F004 IUC4  
F020 A36-003  
F008 T02-24  
F009 T23-16  
F010 T24-03  
F011 T38-10  
F013 1997  
F014 104 weeks  
F015 continuous in the feed  
F017 2.5 and 5% in the diet  
F018 T27-07  
F022 T33-02  
EOR  
F001 40  
F002 6  
F003 12-09-2010  
F004 IUC4  
F020 A36-005  
F021 2  
F007 A01-03: Residual base oils  
F008 T02-18  
F009 T23-48: CF No. 1  
F010 T24-01  
F011 T38-01  
F013 1991  
F014 18 months  
F015 Three times weekly  
F017 0.1ml/application  
F018 T27-07  
F019 A03-02  
F022 T33-02  
EOR  
F001 40  
F002 7  
F003 06-09-2002  
F004 IUC4  
F020 A36-005  
F021 3  
F007 A01-03: Canthus 210 a Deasphalted, dewaxed, residual oil  
F008 T02-18  
F009 T23-07  
F010 T24-02  
F011 T38-01  
F015 3 times weekly  
F017 25 µl per application  
F018 T27-07  
F019 A03-02  
F022 T33-02  
EOB  
C  
B512 TO\_REPRODUCTION\_TAB  
F001 40

F002 1  
F003 12-09-2010  
F004 IUC4  
F037 A36-003  
F007 A01-03: Chevron 100 neutral (refined) CAS 64742-54-7  
F008 T41-02  
F009 T02-24  
F010 T23-42  
F011 T24-03  
F012 T25-03  
F013 T40-05: OECD Guideline 421, Reproductive/Developmental Toxicity screening  
\* test  
F014 1995  
F015 Daily  
F019 1.15 mg/kg  
F020 T27-01  
F035 A03-03  
EOR  
F001 40  
F002 2  
F003 13-02-2003  
F004 IUC4  
F037 A36-003  
F007 A01-03: White oil CAS 8012-95-1  
F008 T41-02  
F009 T02-24  
F010 T23-42  
F011 T24-03  
F012 T25-03  
F036 13 weeks prior to mating  
F014 1987  
F015 5 times weekly  
F016 13 weeks  
F017 13 weks  
F018 one generation after 13 weeks dosing  
F019 5 ml/kg  
F020 T27-01  
F035 A03-02  
F054 1  
EOB  
C  
B513 TO\_DEVELOPMENTAL\_TAB  
F001 40  
F002 1  
F003 13-02-2003  
F004 IUC4  
F030 A36-003  
F007 A01-03: White oil CAS 8012-95-1  
F008 T02-24  
F009 T23-42  
F010 T24-01  
F011 T25-03  
F013 1987  
F015 Days 6 through 19 of gestation  
F016 daily  
F029 A03-02  
EOB

C  
 B019 TO\_SPEC\_INVEST\_TAB  
 F001 40  
 F002 1  
 F003 24-08-2023  
 F004 IUC4  
 EOB  
 C  
 B514 TO\_OTHER\_TAB  
 F001 40  
 F002 1  
 F003 30-01-2002  
 F004 IUC31  
 F008 A36-003  
 F009 3  
 F007 T45-12: Developmental toxicity screen on Heavy vacuum gas oil  
 EOR  
 F001 40  
 F002 2  
 F003 11-10-2002  
 F004 IUC4  
 F009 1  
 F007 T45-12: Correlation of toxicity with chemical components of refinery  
 \* streams  
 EOR  
 F001 40  
 F002 3  
 F003 04-11-2002  
 F004 IUC4  
 F008 A36-003  
 F009 2  
 F007 T45-12: 90-day study on Heavy vacuum gas oil  
 EOB  
 C  
 B601 TEXT\_TAB  
 F002 40  
 F010 1.1.1  
 F004 1  
 F005 AD  
 F006 Phys.chem.data.doc  
 F007 Phys.chem.data.doc  
 F020 3605  
 F021 Phys.chem.data  
 F022 20992  
 F023 11:2:2003 19:15  
 F024 doc  
 EOR  
 F002 40  
 F010 1.1.1  
 F004 1  
 F005 RE  
 F006 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F007 CONCAWE (1997)  
 \*\* Lubricating oil basestocks

\*\* Product dossier No. 97/108

\*\* CONCAWE, Brussels

F020 3603

EOR

F002 40

F010 1.1.1

F004 1

F005 RM

F006 The group of base oils consists of products that are derived  
\*\* from both distillates and residues of the vacuum  
\*\* distillation process in petroleum refining.  
\*\*

\*\* Base oils consist predominantly of hydrocarbons but may also  
\*\* contain small quantities

F007 The group of base oils consists of products that are derived  
\*\* from both distillates and residues of the vacuum  
\*\* distillation process in petroleum refining.  
\*\*

\*\* Base oils consist predominantly of hydrocarbons but may also  
\*\* contain small quantities of sulfur and nitrogen compounds  
\*\* with traces of a number of metals. The oils contain complex  
\*\* hydrocarbons with variable mixtures of paraffins, naphthenes  
\*\* and aromatics with carbon numbers in the range 15 to 50.  
\*\* Hydrocarbon constituents derived from vacuum distillates  
\*\* boil generally in the range 300 to 600 °C, whereas those  
\*\* derived from residual oils may boil up to 800 °C.  
\*\*

\*\* Unrefined vacuum distillates contain polycyclic aromatic  
\*\* compounds (PACs) which are removed during any subsequent  
\*\* refining process. The more severe the refining, the lower  
\*\* the PAC content will be of the refined base oil.  
\*\*

\*\* Physical chemical data for a range of base oils have been  
\*\* summarized by CONCAWE and these are tabulated in the  
\*\* attached document.  
\*\*

\*\* For most of the mammalian toxicology endpoints, information  
\*\* has been used that was derived by the American Petroleum  
\*\* Institute on a wide range of base oils. For simplicity, this  
\*\* robust summary contains detailed information on an API  
\*\* sample of an unrefined distillate (high PAC) and an API  
\*\* sample of a highly refined distillate (low PAC). If data  
\*\* was available on other samples, it has either been  
\*\* summarized in tabular form in the relevant sections of this  
\*\* summary or discussed in detail when appropriate.  
\*\*

\*\* The API sample of highly refined base oil for which data  
\*\* have  
\*\* been selected is one with a low average molecular weight  
\*\* since this is likely to represent the worst case from a  
\*\* toxicological perspective.  
\*\*

\*\* The physico-chemical characteristics of the two samples are  
\*\* as follows:  
\*\*

\*\*  
oil                      Method              Unrefined      Highly  
                         refined

```

**                                     oil
**
** API sample No.                    84-01          83-12
** CAS No.                          64741-50-0      64742-53-6
** API Gravity @60° D287 31.9          25.9
** Density @15°C D287 0.8651          0.8981
** Molecular wt. (gm/mol) D2224 300          260
** Refractive index
** (RI units @20 °C) 1.4815          1.4910
** Total Sulfur (wt. %) D3120 0.38          0.04
** Total Nitrogen (ppm/wt) Chemil 210          38
** Total oxygen (wt.%) NAA 0.038          0.077
** Total Chloride (ppm/wt) coulom 11          2
** Viscosity (cSt @ 40°C) D445 14.07          0.44
** Viscosity (cSt @ 100°C) D445 2.79          2.14
** Pour point (°F) D93 +60          <-20
** Carbon residue (wt. %) D524 0.15          0.14
** Distillation D1160
** IBP (°F) 595          450
** FBP (°F) 810          785

```

```

** Hydrocarbon type analysis
** Nonaromatics (wt. %) D2549 79.1          67.3
** Aromatics (wt. %) D2549 20.9          31.9
** TOTAL 100          100

```

Some oils are destined for food use or pharmaceutical applications and for these the refining process that they undergo is particularly severe to ensure that aromatic materials have been removed and that the resulting oil is colorless. Such oils are known as white oils. Unlike the other base oils in which oral intake is unintentional, the white oils are intended for uses in which an oral intake is likely. For these materials, oral studies are available and, where appropriate, are included in this Robust Summary .

Several individual companies have generated data on environmental effects and ecotoxicity. The relevant CAS descriptions of the materials that have been tested are included in the relevant sections of this robust summary.

F020 3604

EOR

F002 40

F010 1.13

F004 1

F005 RE

F006 IARC (1984)

IARC Monographs on the evaluation of the carcinogenic risk of chemicals to humans, Volume 33: Polynuclear aromatic hydrocarbons, part 2, carbon blacks, mineral oils (lubricant base oils and derived products) and some nitroarenes

F007 IARC (1984)

IARC Monographs on the evaluation of the carcinogenic risk of chemicals to humans, Volume 33: Polynuclear aromatic hydrocarbons, part 2, carbon blacks, mineral oils (lubricant

\*\* base oils and derived products) and some nitroarenes.  
 \*\* International Agency for Research on Cancer, Lyon.  
 F020 3606  
 EOR  
 F002 40  
 F010 1.13  
 F004 3  
 F005 RE  
 F006 Bingham, E. Trosset, R. P., Warshawsky, D. (1980)  
 \*\* Carcinogenic potential of petroleum hydrocarbons, a critical  
 \*\* review of the literature.  
 \*\* J. Environmental Pathology and Toxicology, Vol 3, pp  
 \*\* 483-563.  
 F007 Bingham, E. Trosset, R. P., Warshawsky, D. (1980)  
 \*\* Carcinogenic potential of petroleum hydrocarbons, a critical  
 \*\* review of the literature.  
 \*\* J. Environmental Pathology and Toxicology, Vol 3, pp  
 \*\* 483-563.  
 F020 3607  
 EOR  
 F002 40  
 F010 1.13  
 F004 4  
 F005 RE  
 F006 CONCAWE (1994)  
 \*\* The use of the dimethyl sulphoxide (DMSO) extract by the IP  
 \*\* 346 method as an indicator of the carcinogenicity of  
 \*\* lubricant base oils and distillate aromatic extracts.  
 \*\* CONCAWE Report No. 94/51  
 \*\* CONCAWE, Brussels.  
 F007 CONCAWE (1994)  
 \*\* The use of the dimethyl sulphoxide (DMSO) extract by the IP  
 \*\* 346 method as an indicator of the carcinogenicity of  
 \*\* lubricant base oils and distillate aromatic extracts.  
 \*\* CONCAWE Report No. 94/51  
 \*\* CONCAWE, Brussels.  
 F020 3608  
 EOR  
 F002 40  
 F010 1.13  
 F004 4  
 F005 RE  
 F006 EU (1994)  
 \*\* Commission Directive 94/69/EC of 19 December 1994 adapting  
 \*\* to technical progress for the 21st time Council Directive  
 \*\* 67/548/EEC on the approximation of the laws, regulations and  
 \*\* administrative provisions relating to the classifica  
 F007 EU (1994)  
 \*\* Commission Directive 94/69/EC of 19 December 1994 adapting  
 \*\* to technical progress for the 21st time Council Directive  
 \*\* 67/548/EEC on the approximation of the laws, regulations and  
 \*\* administrative provisions relating to the classification,  
 \*\* packaging and labelling of dangerous substances.  
 \*\* Official Journal of the European Communities No L381,  
 \*\* 31.12.1994  
 F020 3609  
 EOR

F002 40  
 F010 1.13  
 F004 4  
 F005 RM  
 F006 The DMSO method was adopted subsequently in the EU to  
 \*\* distinguish between carcinogenic and non-carcinogenic oils  
 \*\* for classification and labeling purposes.  
 F007 The DMSO method was adopted subsequently in the EU to  
 \*\* distinguish between carcinogenic and non-carcinogenic oils  
 \*\* for classification and labeling purposes.  
 F020 3610  
 EOR  
 F002 40  
 F010 1.13  
 F004 5  
 F005 RE  
 F006 JECFA (1996)  
 \*\* Toxicological evaluation of certain food additives and  
 \*\* contaminants. Prepared by the 44th meeting of the Joint  
 \*\* FAO/WHO Expert Committee on Food Additives (JECFA).  
 \*\* WHO Food Additives Series 35. Geneva.  
 F007 JECFA (1996)  
 \*\* Toxicological evaluation of certain food additives and  
 \*\* contaminants. Prepared by the 44th meeting of the Joint  
 \*\* FAO/WHO Expert Committee on Food Additives (JECFA).  
 \*\* WHO Food Additives Series 35. Geneva.  
 F020 3611  
 EOR  
 F002 40  
 F010 1.13  
 F004 5  
 F005 RE  
 F006 SCF (1995)  
 \*\* Opinion on mineral and synthetic hydrocarbons (expressed on  
 \*\* 22 September 1995)  
 \*\* CS/ADD/MsAd/132-Final, Brussels, European Commission  
 F007 SCF (1995)  
 \*\* Opinion on mineral and synthetic hydrocarbons (expressed on  
 \*\* 22 September 1995)  
 \*\* CS/ADD/MsAd/132-Final, Brussels, European Commission  
 F020 3612  
 EOR  
 F002 40  
 F010 1.13  
 F004 6  
 F005 RE  
 F006 WHO (1982)  
 \*\* Selected Petroleum Products  
 \*\* Environ. Health Criteria Document No. 20.  
 \*\* World Health Organization, Geneva  
 F007 WHO (1982)  
 \*\* Selected Petroleum Products  
 \*\* Environ. Health Criteria Document No. 20.  
 \*\* World Health Organization, Geneva  
 F020 3613  
 EOR  
 F002 40

F010 1.8.1  
F004 1  
F005 RE  
F006 ACGIH (1998)  
\*\* 1998 TLVs and BEIs Threshold limit values for chemical  
\*\* substances and physical agents.  
F007 ACGIH (1998)  
\*\* 1998 TLVs and BEIs Threshold limit values for chemical  
\*\* substances and physical agents.  
F008 IUC4  
F009 11-09-2010  
F020 3614  
EOR  
F002 40  
F010 1.8.1  
F004 1  
F005 RM  
F006 A TWA TLV of 0.005 mg/m3 is proposed for the sum total of 15  
\*\* polynuclear aromatic hydrocarbons (PAHs) listed as  
\*\* carcinogens by the U.S. National Toxicology Program (NTP).  
F007 A TWA TLV of 0.005 mg/m3 is proposed for the sum total of 15  
\*\* polynuclear aromatic hydrocarbons (PAHs) listed as  
\*\* carcinogens by the U.S. National Toxicology Program (NTP).  
F008 IUC4  
F020 3615  
EOR  
F002 40  
F010 2.1  
F004 1  
F005 RE  
F006 American Society for Testing and Materials (ASTM). (1999)  
\*\* Standard Test Method for Pour Point of Petroleum Oils.  
\*\* ASTM D97, Volume 05.01, ASTM, West Conshohocken, PA.  
F007 American Society for Testing and Materials (ASTM). (1999)  
\*\* Standard Test Method for Pour Point of Petroleum Oils.  
\*\* ASTM D97, Volume 05.01, ASTM, West Conshohocken, PA.  
F008 IUC4  
F020 3616  
EOR  
F002 40  
F010 2.1  
F004 1  
F005 RE  
F006 American Society for Testing and Materials (ASTM). (2002)  
\*\* Standard Test Method for Pour Point of Petroleum Products  
\*\* (Rotational Method).  
\*\* ASTM D5985-02, Volume 05.01, ASTM, West Conshohocken, PA.  
F007 American Society for Testing and Materials (ASTM). (2002)  
\*\* Standard Test Method for Pour Point of Petroleum Products  
\*\* (Rotational Method).  
\*\* ASTM D5985-02, Volume 05.01, ASTM, West Conshohocken, PA.  
F008 IUC4  
F020 3617  
EOR  
F002 40  
F010 2.1  
F004 1

F005 RE  
F006 CONCAWE (1997)  
\*\* Lubricating oil basestocks  
\*\* Product dossier No. 97/108  
\*\* CONCAWE, Brussels  
F007 CONCAWE (1997)  
\*\* Lubricating oil basestocks  
\*\* Product dossier No. 97/108  
\*\* CONCAWE, Brussels  
F008 IUC4  
F020 3618  
EOR  
F002 40  
F010 2.1  
F004 1  
F005 RL  
F006 Results of standard method testing was reported in a  
\*\* reliable review dossier.  
F007 Results of standard method testing was reported in a  
\*\* reliable review dossier.  
F008 IUC4  
F020 3619  
EOR  
F002 40  
F010 2.1  
F004 1  
F005 RM  
F006 By definition, melting point is the temperature at which a  
\*\* solid becomes a liquid at normal atmospheric pressure. For  
\*\* complex mixtures like petroleum products, melting point may  
\*\* be characterized by a range of temperatures reflecting the  
\*\* me  
F007 By definition, melting point is the temperature at which a  
\*\* solid becomes a liquid at normal atmospheric pressure. For  
\*\* complex mixtures like petroleum products, melting point may  
\*\* be characterized by a range of temperatures reflecting the  
\*\* melting points of the individual components. To better  
\*\* describe phase or flow characteristics of petroleum  
\*\* products, the pour point is routinely used. The pour point  
\*\* is the lowest temperature at which movement of the test  
\*\* specimen is observed under prescribed conditions of the test  
\*\* (ASTM 2002). In addition, the pour point methodology defines  
\*\* a "no-flow" point, defined as the temperature of the test  
\*\* specimen at which a wax crystal structure or viscosity  
\*\* increase, or both, impedes movement of the surface of the  
\*\* test specimen under the conditions of the test (ASTM 2002).  
\*\* Because not all petroleum products contain wax in their  
\*\* composition, the pour point determination encompasses either  
\*\* change in physical state (i.e., crystal formation) and/or  
\*\* viscosity property.  
F008 IUC4  
F020 3620  
EOR  
F002 40  
F010 2.1  
F004 1  
F005 RS

F006 See following Table and Remarks Section

**		
**	Distillate Oils	Pour Point, °C
**	Solvent de-waxed, light paraffinic	
**	(CAS No. 64742-56-9)	-18
**		
**	Solvent de-waxed, heavy paraffinic	
**	(CAS No. 64742-65-0)	-12
**		
**	Hydrotreated, light paraffinic	

F007 See following Table and Remarks Section

**		
**	Distillate Oils	Pour Point, °C
**	Solvent de-waxed, light paraffinic	
**	(CAS No. 64742-56-9)	-18
**		
**	Solvent de-waxed, heavy paraffinic	
**	(CAS No. 64742-65-0)	-12
**		
**	Hydrotreated, light paraffinic	
**	(CAS No. 64742-55-8)	-18
**		
**	Hydrotreated, heavy paraffinic	
**	(CAS No. 64742-54-7)	-9
**		
**	Hydrotreated, light naphthenic	
**	(CAS No. 64742-53-6)	-60
**		
**	Hydrotreated, heavy naphthenic	
**	(CAS No. 64742-52-5)	-24
**		
**	White mineral oil	
**	(CAS No. 8042-47-5)	-15
**		
**	Residual Oils	
**	Solvent de-waxed	
**	(CAS No. 64742-62-7)	-6
**		

F008 IUC4

F020 3621

EOR

F002 40

F010 2.2

F004 1

F005 RE

F006 CONCAWE (1997)

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F007 CONCAWE (1997)

\*\* Lubricating oil basestocks

\*\* Product dossier No. 97/108

\*\* CONCAWE, Brussels

F008 IUC4

F020 3622

EOR

F002 40

F010 2.2  
 F004 1  
 F005 RE  
 F006 US EPA. (2000)  
 \*\* EPI (Estimation Programs Interface for Windows) Suite,  
 \*\* V3.10, Subroutine MPBPWIN V1.40.  
 \*\* U.S. Environmental Protection Agency, Office of Pollution  
 \*\* Prevention and Toxics, Washington, DC.  
 F007 US EPA. (2000)  
 \*\* EPI (Estimation Programs Interface for Windows) Suite,  
 \*\* V3.10, Subroutine MPBPWIN V1.40.  
 \*\* U.S. Environmental Protection Agency, Office of Pollution  
 \*\* Prevention and Toxics, Washington, DC.  
 F008 IUC4  
 F020 3623  
 EOR  
 F002 40  
 F010 2.2  
 F004 1  
 F005 RM  
 F006 The substances covered in lubricating base oils are complex  
 \*\* and variable mixtures of paraffins, naphthenes  
 \*\* (cycloparaffins), and aromatics having carbon numbers  
 \*\* ranging from about 15 to 50. Because they are mixtures,  
 \*\* lubricating base oils  
 F007 The substances covered in lubricating base oils are complex  
 \*\* and variable mixtures of paraffins, naphthenes  
 \*\* (cycloparaffins), and aromatics having carbon numbers  
 \*\* ranging from about 15 to 50. Because they are mixtures,  
 \*\* lubricating base oils do not have a single numerical value  
 \*\* for boiling point, but rather a boiling range that reflects  
 \*\* the individual components. Base oils are produced from  
 \*\* vacuum distillation of the residue obtained after the  
 \*\* atmospheric distillation of crude oil. The vacuum  
 \*\* distillates and the vacuum residues together form the  
 \*\* general group of unrefined or mildly refined base oil.  
 \*\* Additional treatments or refinements such as solvent  
 \*\* extraction, dewaxing, and hydrogenation, are employed to  
 \*\* produce oils with desirable properties. The ranges of  
 \*\* components modeled using MPBPWIN V1.40 are given in the  
 \*\* table above. Those values are consistent with information  
 \*\* provided by CONCAWE (1997) that indicated component  
 \*\* hydrocarbons of oils produced from vacuum distillation have  
 \*\* boiling points ranging from 300 to 600°C whereas those  
 \*\* produced from vacuum residues contain components with  
 \*\* boiling points as high as 800°C (CONCAWE 1997).  
 F008 IUC4  
 F020 3624  
 EOR  
 F002 40  
 F010 2.2  
 F004 1  
 F005 RS  
 F006 See Remarks Section  
 \*\* Calculated Boiling Point Ranges, °C:  
 \*\* C15 to C50 Paraffinic: 250 to 682  
 \*\* C15 to C50 Naphthenic: 282 to 683

\*\* C15 TO C50 Aromatic: 312 to 788  
 F007 See Remarks Section  
 \*\* Calculated Boiling Point Ranges, °C:  
 \*\* C15 to C50 Paraffinic: 250 to 682  
 \*\* C15 to C50 Naphthenic: 282 to 683  
 \*\* C15 TO C50 Aromatic: 312 to 788  
 F008 IUC4  
 F020 3625  
 EOR  
 F002 40  
 F010 2.4  
 F004 1  
 F005 RE  
 F006 Hazleton UK for Shell Research Ltd. (1991)  
 \*\* Determination of Vapour Pressure.  
 \*\* Report No. 6736-579/70.  
 F007 Hazleton UK for Shell Research Ltd. (1991)  
 \*\* Determination of Vapour Pressure.  
 \*\* Report No. 6736-579/70.  
 F008 IUC4  
 F020 3626  
 EOR  
 F002 40  
 F010 2.4  
 F004 1  
 F005 RS  
 F006 Three runs on the sample were conducted. There was initially  
 \*\* substantial reduction (equivalent to 3°C temperature change)  
 \*\* of estimated VP on prolonged pumping after Run 1 but this  
 \*\* was reduced to the equivalent of 0.65°C change between Runs  
 F007 Three runs on the sample were conducted. There was initially  
 \*\* substantial reduction (equivalent to 3°C temperature change)  
 \*\* of estimated VP on prolonged pumping after Run 1 but this  
 \*\* was reduced to the equivalent of 0.65°C change between Runs  
 \*\* 2 and 3. The latter runs provided values at room temperature  
 \*\* of 1.882 and 1.563 x 10<sup>-4</sup> Pascals, yielding a mean value of  
 \*\*  $V_p(298.15K) = 1.723 \times 10^{-4}$  Pascals. The condensation rates  
 \*\* onto the pan observed in Run 3 increased with temperature  
 \*\* more rapidly than the mass difference indicating an  
 \*\* increasing efficiency of condensation and thus precluding  
 \*\* the use of the condensation data to produce a satisfactory  
 \*\* VP relation. The final values of rate of condensation were  
 \*\* however equivalent in pressure regime to the mass  
 \*\* differences assuming a rough equality between the numerical  
 \*\* magnitudes of temperature and molar mass.  
 F008 IUC4  
 F020 3627  
 EOR  
 F002 40  
 F010 2.4  
 F004 1  
 F005 TC  
 F006 The vapor pressure (VP) was determined using a VP balance  
 \*\* based on a CI Electronics micro-balance with a sensitivity  
 \*\* of approximately 0.1 mg. Sample temperature was controlled  
 \*\* electronically (±1°C) over the range from ambient to 250°C.  
 \*\* Mass

F007 The vapor pressure (VP) was determined using a VP balance  
\*\* based on a CI Electronics micro-balance with a sensitivity  
\*\* of approximately 0.1 mg. Sample temperature was controlled  
\*\* electronically ( $\pm 1^{\circ}\text{C}$ ) over the range from ambient to  $250^{\circ}\text{C}$ .  
\*\* Mass readings and temperature were recorded directly onto a  
\*\* 2-channel chart recorder. The VP balance was designed such  
\*\* that on opening the slide across the orifice in the  
\*\* temperature controlled evaporation furnace, the escaping  
\*\* vapor jet was directed at the scale pan. VP was determined  
\*\* directly from the pressure on the scale pan by measuring the  
\*\* difference of mass readings when the slide across the  
\*\* orifice was open and closed. When condensation occurred onto  
\*\* the pan the VP can be calculated from the condensation rate  
\*\* if the molar mass is known. VP of the sample was measured at  
\*\* several temperatures to yield VP curves for subsequent  
\*\* extrapolation to give 298.15K values. Slope and intercept of  
\*\* VP curve were estimated by an unweighted least squares  
\*\* statistical treatment of the data and errors are  $\pm$  standard  
\*\* deviation of the respective quantity. Maximum and minimum  
\*\* values of VP at 298.15K were calculated directly from the VP  
\*\* relationship using the ranges of errors in slope and  
\*\* intercept respectively. The quoted errors in VP at 298.15K  
\*\* were then calculated directly by extrapolation from these  
\*\* values.

F008 IUC4

F020 3628

EOR

F002 40

F010 3.1.1

F004 1

F005 RE

F006 Atkinson, R. (1990).

\*\* Gas-phase tropospheric chemistry of organic compounds: a  
\*\* review

\*\* Atmos. Environ., Vol. 24A, pp. 1-41

F007 Atkinson, R. (1990).

\*\* Gas-phase tropospheric chemistry of organic compounds: a  
\*\* review

\*\* Atmos. Environ., Vol. 24A, pp. 1-41

F008 IUC4

F020 3629

EOR

F002 40

F010 3.1.1

F004 1

F005 RE

F006 CONCAWE (2001).

\*\* Environmental Classification Of Petroleum Substances

\*\* -Summary Data And Rationale

\*\* Report 01/54,

F007 CONCAWE (2001).

\*\* Environmental Classification Of Petroleum Substances

\*\* -Summary Data And Rationale

\*\* Report 01/54,

F008 IUC4

F009 11-09-2010

F020 3630

EOR
F002 40
F010 3.1.1
F004 1
F005 RE
F006 U.S. EPA. (2001).
\*\* EPI (Estimation Programs Interface) Suite, V3.10. U.S.
\*\* Environmental Protection Agency, Office of Pollution
\*\* Prevention and Toxics, Washington, DC.
F007 U.S. EPA. (2001).
\*\* EPI (Estimation Programs Interface) Suite, V3.10. U.S.
\*\* Environmental Protection Agency, Office of Pollution
\*\* Prevention and Toxics, Washington, DC.
F008 IUC4
F020 3631
EOR
F002 40
F010 3.1.1
F004 1
F005 RL
F006 The predicted endpoint was determined using a validated
\*\* computer model.
F007 The predicted endpoint was determined using a validated
\*\* computer model.
F008 IUC4
F020 3632
EOR
F002 40
F010 3.1.1
F004 1
F005 RM
F006 AOPWIN V1.90 calculates atmospheric oxidation half lives of
\*\* hydrocarbons in contact with hydroxyl radicals in the
\*\* troposphere, under the influence of sunlight. Atmospheric
\*\* oxidation rates were calculated for the lowest molecular
\*\* weight cons
F007 AOPWIN V1.90 calculates atmospheric oxidation half lives of
\*\* hydrocarbons in contact with hydroxyl radicals in the
\*\* troposphere, under the influence of sunlight. Atmospheric
\*\* oxidation rates were calculated for the lowest molecular
\*\* weight constituents, i.e., C15 hydrocarbon components.
\*\* Although the low vapor pressures of these base oils
\*\* indicate that volatilization will not be a very significant
\*\* fate process, oxidation half-lives indicate this may be a
\*\* moderate removal process if these substances were introduced
\*\* to the atmosphere by adsorption to particulate matter via
\*\* atmospheric emissions. The half-lives for degradation of
\*\* these hydrocarbons by reaction with hydroxyl radicals, in
\*\* the troposphere, under the influence of sunlight, will all
\*\* be less than one day, by extrapolation from the data quoted
\*\* by Atkinson (1990).
\*\*
\*\* In general, most products in the base oil category do not
\*\* contain component molecules that will undergo direct
\*\* photolysis. Saturated hydrocarbons (paraffins and
\*\* naphthenics), and single ring aromatics, which constitute
\*\* the majority of these components, do not absorb appreciable

\*\* light energy above 290 nm. Therefore, direct photolysis will  
 \*\* not contribute to a measurable degradative removal of  
 \*\* chemical components in this category from the environment.  
 F008 IUC4  
 F020 3633  
 EOR  
 F002 40  
 F010 3.1.1  
 F004 1  
 F005 RS  
 F006 Indirect photolysis at 25 °C  
 \*\* Concentration of sensitizer:  $1.50 \times 10^6$  OH radicals/cm<sup>3</sup>  
 \*\* Rate constant:  $18.1757 \times 10^{-12}$  cm<sup>3</sup>/mol-sec  
 \*\* Half-life: 0.053 - 0.66 days for C15 hydrocarbon  
 \*\* constituents  
 F007 Indirect photolysis at 25 °C  
 \*\* Concentration of sensitizer:  $1.50 \times 10^6$  OH radicals/cm<sup>3</sup>  
 \*\* Rate constant:  $18.1757 \times 10^{-12}$  cm<sup>3</sup>/mol-sec  
 \*\* Half-life: 0.053 - 0.66 days for C15 hydrocarbon  
 \*\* constituents  
 F008 IUC4  
 F020 3634  
 EOR  
 F002 40  
 F010 3.1.2  
 F004 1  
 F005 CL  
 F006 Hydrolysis of an organic chemical is the transformation  
 \*\* process in which a water molecule or hydroxide ion reacts to  
 \*\* form a new carbon-oxygen bond. Chemicals that have a  
 \*\* potential to hydrolyze include alkylhalides, amides,  
 \*\* carbamates, carbo  
 F007 Hydrolysis of an organic chemical is the transformation  
 \*\* process in which a water molecule or hydroxide ion reacts to  
 \*\* form a new carbon-oxygen bond. Chemicals that have a  
 \*\* potential to hydrolyze include alkylhalides, amides,  
 \*\* carbamates, carboxylic acid esters and lactones, epoxides,  
 \*\* phosphate esters, and sulfonic acid esters. The chemical  
 \*\* components that comprise the base oil category are  
 \*\* hydrocarbons, which are not included in these chemical  
 \*\* groups, and they are not subject to hydrolysis reactions  
 \*\* with water.  
 F008 IUC4  
 F020 3635  
 EOR  
 F002 40  
 F010 3.1.2  
 F004 1  
 F005 RE  
 F006 Harris, J.C. (1982).  
 \*\* Rate of Hydrolysis. In Handbook of Chemical Property  
 \*\* Estimation Methods. p. 7-6.  
 \*\* W. J. Lyman, W.F. Reehl and D.H. Rosenblatt, eds.  
 \*\* McGraw-Hill Book Company, New York, NY, USA.  
 F007 Harris, J.C. (1982).  
 \*\* Rate of Hydrolysis. In Handbook of Chemical Property  
 \*\* Estimation Methods. p. 7-6.

\*\* W. J. Lyman, W.F. Reehl and D.H. Rosenblatt, eds.  
 \*\* McGraw-Hill Book Company, New York, NY, USA.  
 F008 IUC4  
 F020 3636  
 EOR  
 F002 40  
 F010 3.1.2  
 F004 1  
 F005 RS  
 F006 Measured value: N/A  
 \*\* Degradation %: N/A  
 \*\* Half-life: N/A  
 \*\* Breakdown products: N/A  
 F007 Measured value: N/A  
 \*\* Degradation %: N/A  
 \*\* Half-life: N/A  
 \*\* Breakdown products: N/A  
 F008 IUC4  
 F020 3637  
 EOR  
 F002 40  
 F010 3.3.1  
 F004 2  
 F005 AD  
 F006 Distribution.doc  
 F007 Distribution.doc  
 F008 IUC4  
 F020 3638  
 F021 AD2114  
 F022 36352  
 F023 7:2:2003 11:4  
 F024 doc  
 EOR  
 F002 40  
 F010 3.3.1  
 F004 2  
 F005 AD  
 F006 fugacity graph.doc  
 F007 fugacity graph.doc  
 F008 IUC4  
 F020 3639  
 F021 AD2115  
 F022 91136  
 F023 7:2:2003 11:4  
 F024 doc  
 EOR  
 F002 40  
 F010 3.3.1  
 F004 2  
 F005 CL  
 F006 This complex petroleum mixture is expected to partition  
 \*\* primarily to soil and/or sediment.  
 F007 This complex petroleum mixture is expected to partition  
 \*\* primarily to soil and/or sediment.  
 F008 IUC4  
 F020 3640  
 EOR

F002 40  
 F010 3.3.1  
 F004 2  
 F005 RE  
 F006 CONCAWE (2001).  
 \*\* Environmental Classification Of Petroleum Substances  
 \*\* -Summary Data And Rationale  
 \*\* Report 01/54,  
 F007 CONCAWE (2001).  
 \*\* Environmental Classification Of Petroleum Substances  
 \*\* -Summary Data And Rationale  
 \*\* Report 01/54,  
 F008 IUC4  
 F020 3641  
 EOR  
 F002 40  
 F010 3.3.1  
 F004 2  
 F005 RE  
 F006 Trent University. (1999)  
 \*\* Level 1 Fugacity-Based Environmental Equilibrium  
 \*\* Partitioning Model, V2.11.  
 \*\* Environmental Modelling Centre, Trent University, Canada.  
 F007 Trent University. (1999)  
 \*\* Level 1 Fugacity-Based Environmental Equilibrium  
 \*\* Partitioning Model, V2.11.  
 \*\* Environmental Modelling Centre, Trent University, Canada.  
 F008 IUC4  
 F020 3642  
 EOR  
 F002 40  
 F010 3.3.1  
 F004 2  
 F005 RL  
 F006 The predicted endpoint was determined using a validated  
 \*\* computer model.  
 F007 The predicted endpoint was determined using a validated  
 \*\* computer model.  
 F008 IUC4  
 F020 3643  
 EOR  
 F002 40  
 F010 3.3.1  
 F004 2  
 F005 RM  
 F006 Model based on chemical fugacity. Multimedia distribution  
 \*\* was calculated for C15 hydrocarbons, the lowest molecular  
 \*\* components found in base oils. Larger molecular weight  
 \*\* components are expected to exhibit greater partitioning  
 \*\* behavior to t  
 F007 Model based on chemical fugacity. Multimedia distribution  
 \*\* was calculated for C15 hydrocarbons, the lowest molecular  
 \*\* components found in base oils. Larger molecular weight  
 \*\* components are expected to exhibit greater partitioning  
 \*\* behavior to terrestrial media. Mobility in the aquatic and  
 \*\* atmospheric environment is low due to low water solubility  
 \*\* and low vapor pressure. These components will partition

\*\* rapidly to the terrestrial compartment, where the main fate  
 \*\* process is expected to be slow biodegradation of base oil  
 \*\* components in soil and sediment.  
 \*\*  
 \*\* A summary of the EQC modeling of the distribution and  
 \*\* transport between environmental compartments for selected  
 \*\* hydrocarbon compounds in lubricant base oils is presented in  
 \*\* the attached table and graph. The compounds selected for  
 \*\* modeling represent various C15 compounds in base oils (e.g.,  
 \*\* linear and branched paraffins, naphthenes and aromatic  
 \*\* hydrocarbons).  
 F008 IUC4  
 F020 3644  
 EOR  
 F002 40  
 F010 3.3.1  
 F004 2  
 F005 RS  
 F006 Medium % distribution  
 \*\* Air: 0 to 94  
 \*\* Soil: 6 to 97  
 \*\* Water: 0.88 to <0.0001  
 \*\* Sediment <0.1 to 2  
 \*\* Suspended Sediment <0.02 to 0.004  
 F007 Medium % distribution  
 \*\* Air: 0 to 94  
 \*\* Soil: 6 to 97  
 \*\* Water: 0.88 to <0.0001  
 \*\* Sediment <0.1 to 2  
 \*\* Suspended Sediment <0.02 to 0.004  
 F008 IUC4  
 F020 3645  
 EOR  
 F002 40  
 F010 3.5  
 F004 1  
 F005 RE  
 F006 Shell Research Ltd. (1986)  
 \*\* Base Oils: An Assessment of Ready Biodegradability. Report  
 \*\* No. SBGR.86.137.  
 F007 Shell Research Ltd. (1986)  
 \*\* Base Oils: An Assessment of Ready Biodegradability. Report  
 \*\* No. SBGR.86.137.  
 F008 IUC4  
 F020 3646  
 EOR  
 F002 40  
 F010 3.5  
 F004 1  
 F005 RL  
 F006 The study report lacked an extensive description of  
 \*\* experimental procedures but instead referenced procedures  
 \*\* detailed in a laboratory SOP.  
 F007 The study report lacked an extensive description of  
 \*\* experimental procedures but instead referenced procedures  
 \*\* detailed in a laboratory SOP.  
 F008 IUC4

EOR

F010 3.5

F005 RS

F006 The

F007 The test substance was partially degraded to 20-26% of the  
 \*\* theoretical CO2 in 28 days. Degradation commenced after a  
 \*\* lag period of 2 days. Biodegradation curve showed that  
 \*\* degradation had virtually stopped by day 28. Test substance  
 \*\* was therefore inherently biodegradable since it achieved  
 \*\* >20% biodegradability based upon CO2 evolution.

**		% Degradation	Mean	
**	Sample	(day 28)	% Degraded	
**	Test substance		26, 20	23
**	Na Benzoate	86, 92	89	

F020 3648

F002

F004 1

F006 The

F007 The test substance was added to test medium from a stock solution containing 2.4 g/l emulsified in Dobane PT sulphonate (2 mg/l), a non-biodegradable detergent. The final test concentration of the base oil was 20 mg/l. The test medium was dispensed into Sturm vessels, inoculated and aerated with 60 ml/min of CO<sub>2</sub>-free air and incubated at 20 ± 1°C. Biodegradation was determined on days 1, 2, 5, 9, 14, 20, and 28 by titrating the total CO<sub>2</sub> released. The medium was acidified on day 27 to release the total CO<sub>2</sub> by day 28. Test substance, control blank, and sodium benzoate control (20 mg/l) were tested in duplicates. The empirical formula used was C<sub>n</sub>H<sub>2n+1</sub> which yielded a theoretical CO<sub>2</sub> evolution of 3.14 g CO<sub>2</sub> per g of test substance.

F020 3649

F002

F004 3

F006 Ex:

F007 Exxon Biomedical Sciences, Inc. (1995)

F007 Exxon Biomedical Sciences, Inc. (1995)

\*\* Ready Biodegradability, Manometric Respirometry.  
 \*\* Study #198194A.  
 F008 IUC4  
 F020 3650  
 EOR  
 F002 40  
 F010 3.5  
 F004 3  
 F005 RS  
 F006 By day 28, 31% degradation of the test material was observed  
 \*\* and indicated that the test material was inherently  
 \*\* biodegradable.  
 \*\* By day 5, >60% biodegradation of positive control was  
 \*\* observed, which meets the guideline requirement. No  
 \*\* excu  
 F007 By day 28, 31% degradation of the test material was observed  
 \*\* and indicated that the test material was inherently  
 \*\* biodegradable.  
 \*\* By day 5, >60% biodegradation of positive control was  
 \*\* observed, which meets the guideline requirement. No  
 \*\* excursions from the protocol were noted.  
 \*\* Biodegradation was based on net oxygen consumption and the  
 \*\* theoretical oxygen demand of the test material as calculated  
 \*\* using results of an elemental analysis of the test  
 \*\* material.  
 \*\*           % Degradation\*                      Mean % Degradation  
 \*\*       Sample           (day 28)                      (day 28)  
 \*\*       HHP               32.93, 27.2, 33.27   31.13  
 \*\*       Na Benzoate   82.04; 72.88               77.46  
 \*\*  
 \*\*       \* replicate data  
 F008 IUC4  
 F020 3651  
 EOR  
 F002 40  
 F010 3.5  
 F004 3  
 F005 TC  
 F006 Fresh activated sludge was obtained one day prior to test  
 \*\* initiation, and homogenized in a blender for two minutes.  
 \*\* After allowing the sample to settle for approximately 30  
 \*\* minutes, the homogenated supernatant was decanted, avoiding  
 \*\* carry-o  
 F007 Fresh activated sludge was obtained one day prior to test  
 \*\* initiation, and homogenized in a blender for two minutes.  
 \*\* After allowing the sample to settle for approximately 30  
 \*\* minutes, the homogenated supernatant was decanted, avoiding  
 \*\* carry-over of solids. Microbial activity of an aliquot of  
 \*\* the filtered supernatant was 1E6 CFU/ml which was  
 \*\* determined  
 \*\* using microbial agar dip slides. Activated sludge  
 \*\* supernatant was added to the test medium at 10 ml/l and the  
 \*\* inoculated medium was continuously aerated with CO2-free air  
 \*\* until the next day when the test systems were prepared.  
 \*\* Test medium consisted of glass distilled water and mineral  
 \*\* salts (phosphate buffer, ferric chloride, magnesium sulfate,  
 \*\* calcium chloride). Test vessels were 1 Liter glass flasks

\*\* located in a water bath and electronically monitored for  
 \*\* oxygen consumption. Test material was tested in triplicate,  
 \*\* controls and blanks were tested in duplicate. Test material  
 \*\* (hydrotreated heavy paraffinic petroleum distillates, HHP)  
 \*\* concentration was approximately 44 mg/l, equivalent to a  
 \*\* theoretical oxygen demand (ThOD) of 148 mg/l. Test material  
 \*\* was weighed onto a Gelman type A/E 13 mm glass fiber filter  
 \*\* which was then added to each respirometer flask. Sodium  
 \*\* benzoate (positive control) concentration was 53.54 mg/l,  
 \*\* and was added using an aliquot of a stock solution.  
 \*\* Test temperature was 22 ± 1°C. All test vessels were stirred  
 \*\* constantly for 28 days using magnetic stir bars and plates.

F008 IUC4

F020 3652

EOR

F002 40

F010 3.5

F004 7

F005 RE

F006 BP International Limited. (1990)

\*\* Assessment of Ready Biodegradability (Modified Sturm Test).

\*\* Project No. 301/64; Report No. AT301/064.

F007 BP International Limited. (1990)

\*\* Assessment of Ready Biodegradability (Modified Sturm Test).

\*\* Project No. 301/64; Report No. AT301/064.

F008 IUC4

F020 3653

EOR

F002 40

F010 3.5

F004 7

F005 RL

F006 The study was performed following the 1981 guidelines for

\*\* OECD 301B.

F007 The study was performed following the 1981 guidelines for

\*\* OECD 301B.

F008 IUC4

F020 3654

EOR

F002 40

F010 3.5

F004 7

F005 RS

F006 By day 28, the 10 and 20 mg C/L test flasks showed

\*\* biodegradation of 29% and 22%, respectively.

\*\* % Degradation % Degradation % Degradation

\*\* Day Reference 10 ppm 20 ppm

\*\* Test Sub. Test Sub.

\*\* 10 31 0 1

\*\* 21 89 25 12

\*\* 28 89 2

F007 By day 28, the 10 and 20 mg C/L test flasks showed

\*\* biodegradation of 29% and 22%, respectively.

\*\* % Degradation % Degradation % Degradation

\*\* Day Reference 10 ppm 20 ppm

\*\* Test Sub. Test Sub.

\*\* 10 31 0 1

**	21	89	25	12
**	28	89	29	22

\*\*

\*\* The test material was not readily biodegradable. Within a  
 \*\* period of 28 days, 22 and 29% degradation was observed. The  
 \*\* pass limit for this test is 60% within 28 days.

\*\*

\*\* The reference test substance was degraded to 89% by day 28.  
 \*\* The pH of the test cultures (10 mg/l and 20 mg/l) and  
 \*\* controls (sodium benzoate standard and negative control)  
 \*\* measured on Day 27 were 4.8, 4.8, 4.9, and 5.2,  
 \*\* respectively.

F008 IUC4

F020 3655

EOR

F002 40

F010 3.5

F004 7

F005 TC

F006 The test material entered the experimental containers  
 \*\* through direct dispersion in water. Activated sludge  
 \*\* bacteria from the Severn Trent Plc sewage treatment plant in  
 \*\* Belper, Derbyshire was used as the inoculum. The sample  
 \*\* sludge was hom

F007 The test material entered the experimental containers  
 \*\* through direct dispersion in water. Activated sludge  
 \*\* bacteria from the Severn Trent Plc sewage treatment plant in  
 \*\* Belper, Derbyshire was used as the inoculum. The sample  
 \*\* sludge was homogenized in a mixer for 10 minutes prior to a  
 \*\* solid settling phase and a subsequent filtering of the  
 \*\* supernatant for use. The experimental containers had an  
 \*\* inoculum concentration of 1%.

\*\* The exposures lasted for a period of 28 days. The  
 \*\* experimental containers were 5 liter glass culture vessels,  
 \*\* containing 3 liters of a mixture of nutrient medium, test  
 \*\* material, and inoculum. Test conditions were run in  
 \*\* darkness at a constant temperature of 21°C. Nutrient medium  
 \*\* was prepared according to the OECD guideline recipe using  
 \*\* tap water purified by ion exchange and reverse osmosis.  
 \*\* A series of both two controls and two test material  
 \*\* concentrations were run. The controls consisted of a group  
 \*\* with just the culture medium and the inoculum and a group  
 \*\* with culture medium, inoculum, and 20 mg/l Sodium benzoate  
 \*\* (C6H5 \* COONa). The two test concentrations of test  
 \*\* material were 10 and 20 mg/l.

\*\* All culture vessels were sealed and aerated with CO2 free  
 \*\* air at a rate of about 2 bubbles per second. Additionally,  
 \*\* the solution was continuously stirred by magnetic stirrers.  
 \*\* Samples were taken from the first CO2 absorber vessel on  
 \*\* Days 0, 1, 2, 3, 6, 8, 10, 14, 16, 21, 23, 27, and 28.  
 \*\* Samples were taken from the second absorber vessel on Days 0  
 \*\* and 28. The absorbers were made up of 500 ml Dreschel  
 \*\* bottles filled with 350 ml of 0.05M NaOH. The solution was  
 \*\* prepared using purified, degassed water. On day 27, the pH  
 \*\* of each vessel was measured and 1 ml of concentrated HCl was  
 \*\* added to drive off inorganic carbonate. CO2 production (as  
 \*\* inorganic carbon) was measured by an Ionics 555 TOC Analyzer

```

**      in triplicate.
F008 IUC4
F020 3656
EOR
F002 40
F010 3.5
F004 18
F005 RE
F006 BP International Limited. (1991)
**      Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**      L-33-T-82.
**      Report No. BL3975/B, Performing Laboratory Study No. T930/A.
F007 BP International Limited. (1991)
**      Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**      L-33-T-82.
**      Report No. BL3975/B, Performing Laboratory Study No. T930/A.
F008 IUC4
F020 3657
EOR
F002 40
F010 3.5
F004 18
F005 RL
F006 The CEC method is not a test of ready or inherent
**      biodegradability, nor do the test results provide a reliable
**      measure of the extent of ultimate biodegradability, or
**      mineralization. These test results can only indicate
**      primary biodegradati
F007 The CEC method is not a test of ready or inherent
**      biodegradability, nor do the test results provide a reliable
**      measure of the extent of ultimate biodegradability, or
**      mineralization. These test results can only indicate
**      primary biodegradation, i.e., some loss of oil based on
**      concentration analysis of the parent base oil over the
**      course of the study.
F008 IUC4
F020 3658
EOR
F002 40
F010 3.5
F004 18
F005 RS
F006 By day 21, biodegradation of the test substance was 63%,
**      65%, and 61% in the individual flasks. The mean
**      biodegradation was 63%.
**      % Biodegradation
**      Reference Material      Test Substance
**      Day      Rep1  Rep2  Rep3      R
F007 By day 21, biodegradation of the test substance was 63%,
**      65%, and 61% in the individual flasks. The mean
**      biodegradation was 63%.
**      % Biodegradation
**      Reference Material      Test Substance
**      Day      Rep1  Rep2  Rep3      Rep1  Rep2  Rep3  21      27      29      30
**      63      65      61
**
**      Mean:      29      63

```

\*\* Biodegradation of the reference material was 27%, 29%, and  
 \*\* 30% in the individual flasks, and the mean biodegradation  
 \*\* was 29%.  
 \*\* There were no apparent deviations from the given method.  
 F008 IUC4  
 F020 3659  
 EOR  
 F002 40  
 F010 3.5  
 F004 18  
 F005 TC  
 F006 Settled activated sludge acquired from Buckland Sewage  
 \*\* Treatment Works, Milber, Newton Abbot, Devon, was utilized  
 \*\* as the inoculum. The inoculum was normally between 105 and  
 \*\* 107 Colony Forming Units (CFU)/ml. Bacteria were enumerated  
 \*\* by Di  
 F007 Settled activated sludge acquired from Buckland Sewage  
 \*\* Treatment Works, Milber, Newton Abbot, Devon, was utilized  
 \*\* as the inoculum. The inoculum was normally between 105 and  
 \*\* 107 Colony Forming Units (CFU)/ml. Bacteria were enumerated  
 \*\* by Dip Slide (Oxoid, TTC Red Spot) and incubated at 25 ±1°C  
 \*\* until sufficient colonies were visible to enable counting.  
 \*\* The inoculum was used in the experiment at a rate of 1 ml  
 \*\* per flask.  
 \*\* The test medium was prepared following the formula specified  
 \*\* in ISO Standard 7827. Mother solutions of the test  
 \*\* substance and reference oil were prepared by adding 150 g of  
 \*\* test or reference substance to 1 liter of A113  
 \*\* (1,1,2-trichlorotrifluoroethane). The negative control  
 \*\* reference substance was white oil, R.L. 110 (Brixham test  
 \*\* substance #T071). The test design consisted of 5 test flasks  
 \*\* containing 150 ml of test medium, 1 ml inoculum, and 50 ml  
 \*\* of test substance mother solution; 5 reference flasks  
 \*\* containing 150 ml of test medium, 1 ml inoculum, and 50 ml  
 \*\* of reference substance mother solution; 2 blank flasks  
 \*\* containing 150 ml of test medium and 1 ml inoculum; and 1  
 \*\* poisoned flask prepared identical as the test flasks but  
 \*\* contained 1 ml of HgCl<sub>2</sub>. Incubation flasks were 500-ml  
 \*\* conical flasks fitted with foam plugs.  
 \*\* On day 0 of the test, two blank flasks, two test flasks, and  
 \*\* two reference flasks were sacrificed for analysis of  
 \*\* residual oil content by infrared spectrophotometry (see  
 \*\* analysis procedure below). The remaining flasks were placed  
 \*\* on an orbital incubator and maintained at 25 ± 1°C for 21  
 \*\* days. On day 21, the contents of all flasks were analyzed  
 \*\* for residual oil content.  
 \*\*  
 \*\* Analysis Procedure:  
 \*\* Residual oil content (%) in each flask was analyzed using a  
 \*\* method suitable for the determination of hydrocarbon  
 \*\* lubricants in water samples. Lubricants were extracted from  
 \*\* water using 1,1,2 trichlorotrifluoroethane and were analyzed  
 \*\* using infrared spectrophotometry. The samples were  
 \*\* quantified against known standards of the lubricant using  
 \*\* the maximum absorption of the CH<sub>3</sub>-CH<sub>2</sub> band at 2930 ± 10  
 \*\* cm<sup>-1</sup>.  
 \*\* Percent test substance degraded was calculated as

```

**
**      % (ROC) poisoned flask - % ROC test flask   x   100
**                                     %ROC poisoned flask
F008 IUC4
F020 3660
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**      Assessment of Ready Biodegradability (Modified Sturm Test).
**      Project No. 301/10; Report No. AT301/030.
F007 BP International Limited. (1990)
**      Assessment of Ready Biodegradability (Modified Sturm Test).
**      Project No. 301/10; Report No. AT301/030.
F008 IUC4
F020 3661
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**      Assessment of Ready Biodegradability (Modified Sturm Test).
**      Project No. 301/11; Report No. AT301/031.
F007 BP International Limited. (1990)
**      Assessment of Ready Biodegradability (Modified Sturm Test).
**      Project No. 301/11; Report No. AT301/031.
F008 IUC4
F020 3662
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**      Assessment of Ready Biodegradability (Modified Sturm Test).
**      Project No. 301/12; Report No. AT301/034.
F007 BP International Limited. (1990)
**      Assessment of Ready Biodegradability (Modified Sturm Test).
**      Project No. 301/12; Report No. AT301/034.
F008 IUC4
F020 3663
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**      Assessment of Ready Biodegradability (Modified Sturm Test).
**      Project No. 301/13; Report No. AT301/032.
F007 BP International Limited. (1990)
**      Assessment of Ready Biodegradability (Modified Sturm Test).
**      Project No. 301/13; Report No. AT301/032.
F008 IUC4
F020 3664

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EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/15; Report No. AT301/035.  
F007 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/15; Report No. AT301/035.  
F008 IUC4  
F020 3665  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/16; Report No. AT301/036.  
F007 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/16; Report No. AT301/036.  
F008 IUC4  
F020 3666  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/60; Report No. AT301/038.  
F007 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/60; Report No. AT301/038.  
F008 IUC4  
F020 3667  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/64; Report No. AT301/064.  
F007 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/64; Report No. AT301/064.  
F008 IUC4  
F020 3668  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE

F006 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/9; Report No. AT301/029.  
F007 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/9; Report No. AT301/029.  
F008 IUC4  
F020 3669  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/59; Report No. AT301/037.  
F007 BP International Limited. (1990)  
\*\* Assessment of Ready Biodegradability (Modified Sturm Test).  
\*\* Project No. 301/59; Report No. AT301/037.  
F008 IUC4  
F020 3670  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3823/B, Performing Laboratory Study No. T119/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3823/B, Performing Laboratory Study No. T119/A.  
F008 IUC4  
F020 3671  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3820/B, Performing Laboratory Study No. T116/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3820/B, Performing Laboratory Study No. T116/A.  
F008 IUC4  
F020 3672  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1991)

\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3824/B, Performing Laboratory Study No. T120/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3824/B, Performing Laboratory Study No. T120/A.  
F008 IUC4  
F020 3673  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3825/B, Performing Laboratory Study No. T121/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3825/B, Performing Laboratory Study No. T121/A.  
F008 IUC4  
F020 3674  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3970/B, Performing Laboratory Study No. T651/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3970/B, Performing Laboratory Study No. T651/A.  
F008 IUC4  
F020 3675  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3971/B, Performing Laboratory Study No. T652/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3971/B, Performing Laboratory Study No. T652/A.  
F008 IUC4  
F020 3676  
EOR  
F002 40  
F010 3.5

F004 31  
F005 RE  
F006 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3975/B, Performing Laboratory Study No. T930/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3975/B, Performing Laboratory Study No. T930/A.  
F008 IUC4  
F020 3677  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3819/B, Performing Laboratory Study No. T115/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3819/B, Performing Laboratory Study No. T115/A.  
F008 IUC4  
F020 3678  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3821/B, Performing Laboratory Study No. T117/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3821/B, Performing Laboratory Study No. T117/A.  
F008 IUC4  
F020 3679  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3822/B, Performing Laboratory Study No. T118/A.  
F007 BP International Limited. (1991)  
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method  
\*\* L-33-T-82.  
\*\* Report No. BL3822/B, Performing Laboratory Study No. T118/A.  
F008 IUC4  
F020 3680

EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method
\*\* L-33-T-82.
\*\* Report No. BL3826/B, Performing Laboratory Study No. T122/A.
F007 BP International Limited. (1991)
\*\* Mineral Hydrocarbon Oil: Biodegradability by CEC Method
\*\* L-33-T-82.
\*\* Report No. BL3826/B, Performing Laboratory Study No. T122/A.
F008 IUC4
F020 3681
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
\*\* Ready Biodegradability, Manometric Respirometry.
\*\* Study #107194A.
F007 Exxon Biomedical Sciences, Inc. (1995)
\*\* Ready Biodegradability, Manometric Respirometry.
\*\* Study #107194A.
F008 IUC4
F020 3682
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
\*\* Ready Biodegradability, Manometric Respirometry.
\*\* Study #123694A.
F007 Exxon Biomedical Sciences, Inc. (1995)
\*\* Ready Biodegradability, Manometric Respirometry.
\*\* Study #123694A.
F008 IUC4
F020 3683
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
\*\* Ready Biodegradability, Manometric Respirometry.
\*\* Study #107094A.
F007 Exxon Biomedical Sciences, Inc. (1995)
\*\* Ready Biodegradability, Manometric Respirometry.
\*\* Study #107094A.
F008 IUC4
F020 3684
EOR
F002 40
F010 3.5

F004 31  
F005 RE  
F006 Exxon Biomedical Sciences, Inc. (1995)  
\*\* Ready Biodegradability, Manometric Respirometry.  
\*\* Study #198194A.  
F007 Exxon Biomedical Sciences, Inc. (1995)  
\*\* Ready Biodegradability, Manometric Respirometry.  
\*\* Study #198194A.  
F008 IUC4  
F020 3685  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 Shell Research Ltd. (1986)  
\*\* Base Oils: An Assessment of Ready Biodegradability. Report  
\*\* No. SBGR.86.137.  
F007 Shell Research Ltd. (1986)  
\*\* Base Oils: An Assessment of Ready Biodegradability. Report  
\*\* No. SBGR.86.137.  
F008 IUC4  
F020 3686  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RE  
F006 Shell Research Ltd. (1987)  
\*\* Base Oil: An Assessment of Ready Biodegradability. Report  
\*\* No. SBGR.87.259.  
F007 Shell Research Ltd. (1987)  
\*\* Base Oil: An Assessment of Ready Biodegradability. Report  
\*\* No. SBGR.87.259.  
F008 IUC4  
F020 3687  
EOR  
F002 40  
F010 3.5  
F004 31  
F005 RM  
F006 28 biodegradability studies have been reported for base  
\*\* oils.  
\*\* In the preceding paragraphs a full study description is  
\*\* given for each of the methods that have been used.  
\*\*  
\*\* Based on the results of ultimate biodegradability tests  
\*\* using modified  
F007 28 biodegradability studies have been reported for base  
\*\* oils.  
\*\* In the preceding paragraphs a full study description is  
\*\* given for each of the methods that have been used.  
\*\*  
\*\* Based on the results of ultimate biodegradability tests  
\*\* using modified Sturm and manometric respirometry testing  
\*\* these base oils are expected to be, for the most part,  
\*\* inherently biodegradable.

Results of primary biodegradability testing using the CEC test method indicate that transformation of parent base oil due to biological activity occurs to a varying extent, ranging from 13% to 79% loss of original concentrations of tested base oils.

Summarized data for all studies (including those described in the preceding paras) are tabulated below

Method*	Biodeg. (%)	Yes/No	Biodegradable Ref.
Distillates, solvent-refined heavy paraffinic (64741-88-4)			
OECD 301B**	22, 11	No	30
OECD 301B	15, 12	No	25
OECD 301B	8, 8	No	28
OECD 301B	3, 11	No	29
OECD 301B	12, 11	No	26
OECD 301B	9, 8	No	27
CEC L-33-T-82	72	Yes	57
CEC L-33-T-82	71	Yes	58
CEC L-33-T-82	53	Yes	49
CEC L-33-T-82	79	Yes	50
CEC L-33-T-82	64	Yes	59
CEC L-33-T-82	51	Yes	52
Distillates, solvent-refined light paraffinic (64741-89-5)			
OECD 301B	29, 22	No	32
OECD 301B	17, 17	No	33
CEC L-33-T-82	63	Yes	55
CEC L-33-T-82	75	Yes	56
Solvent de-asphalted Bright stock (64741-95-3)			
OECD 301B	11, 4	No	31
CEC L-33-T-82	17	No	54
Distillates, hydrotreated or solvent refined light naphthenic (64741-97-5)			
84\449\EEC, C5	1.5	No	103
Solvent-refined residual oil (64742-01-4)			
OECD 301B	4, 2	No	No Ref
OECD 301B	5, 5	No	44
CEC L-33-T-82	45	Yes	51
CEC L-33-T-82	13	No	53
Distillates, hydrotreated or solvent refined light naphthenic (64742-53-6)			
OECD 301F	42	Yes	80
Distillates, hydrotreated heavy paraffinic (64742-54-7)			
OECD 301F	31	Yes	83
Distillates, solvent dewaxed light paraffinic (64742-56-9)			
OECD 301F	50	Yes	82
Distillate, solvent-dewaxed heavy paraffinic (64742-65-0)			

\*\* 84\449\EEC, C5 23 Yes 102  
 \*\* OECD 301F 38 Yes 81  
 \*\*  
 \*\* White oil, (8042-47-5)  
 \*\* OECD 301B\*\*\* -, 24 Yes cited in 71  
 \*\* CEC L-33-T-82 0 No cited in 71  
 \*\*  
 \*\* \* Methods used are:  
 \*\* OECD 301B Ready, Sturm test  
 \*\* OECD 301F Ready, Manometric method  
 \*\* CEC L-33-T-82 CEC Test  
 \*\* 84\449\EEC, C5 Ready, Sturm Test  
 \*\*  
 \*\* \*\* For method OECD 301B the two values given for  
 \*\* biodegradation are for test material concentrations of 10 and 20 ppm.  
 \*\*  
 \*\* \*\*\* Value only available for 20 ppm concentration  
 F008 IUC4  
 F020 3688  
 EOR  
 F002 40  
 F010 4.1  
 F004 1  
 F005 RE  
 F006 BP International Limited. (1990)  
 \*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
 \*\* Project No. 301/65;  
 \*\* Report No. AT301/044.  
 F007 BP International Limited. (1990)  
 \*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
 \*\* Project No. 301/65;  
 \*\* Report No. AT301/044.  
 F008 IUC4  
 F020 3689  
 EOR  
 F002 40  
 F010 4.1  
 F004 1  
 F005 RL  
 F006 Only one concentration of the test substance was tested.  
 \*\* Results of chemical analyses of test substance  
 \*\* concentrations were not reported.  
 F007 Only one concentration of the test substance was tested.  
 \*\* Results of chemical analyses of test substance  
 \*\* concentrations were not reported.  
 F008 IUC4  
 F020 3690  
 EOR  
 F002 40  
 F010 4.1  
 F004 1  
 F005 RS  
 F006 No mortality at 96 hours in the 0 and 1000 mg/l groups.  
 \*\*  
 \*\* 96 hrs-LL0 = 1000 mg/l, based on nominal loading rates.  
 \*\*  
 \*\* Only one concentration was tested in the limit test. The

\*\* report states that water samples were taken at 0, 24, and 96  
\*\* hours f  
F007 No mortality at 96 hours in the 0 and 1000 mg/l groups.  
\*\*  
\*\* 96 hrs-LL0 = 1000 mg/l, based on nominal loading rates.  
\*\*  
\*\* Only one concentration was tested in the limit test. The  
\*\* report states that water samples were taken at 0, 24, and 96  
\*\* hours for analytical verification of test concentrations,  
\*\* but results of any analyses were not reported.  
F008 IUC4  
F020 3691  
EOR  
F002 40  
F010 4.1  
F004 1  
F005 TC  
F006 Daily renewal of the test media ensured that test material  
\*\* levels were maintained at the exposure concentrations. The  
\*\* test media was introduced into the exposure vessels through  
\*\* direct dispersion in water. Shielded propeller-stirrers  
\*\* were  
F007 Daily renewal of the test media ensured that test material  
\*\* levels were maintained at the exposure concentrations. The  
\*\* test media was introduced into the exposure vessels through  
\*\* direct dispersion in water. Shielded propeller-stirrers  
\*\* were utilized to aid in the dispersion of the test material.  
\*\* Observations indicated that the test material was well  
\*\* dispersed throughout the experiment.  
\*\* 20 ml water samples were drawn from the exposure vessels via  
\*\* a glass syringe and delivered to a storage vessel. The  
\*\* syringe was then rinsed with 20 ml of  
\*\* 1,1,2-trichlorotrifluoroethane. Subsequently, the rinse was  
\*\* mixed with the sample prior to storage. Water samples were  
\*\* collected at 0, 24, and 96 hours into the experiment.  
\*\* Samples were stored at 4°C in glass containers until BP  
\*\* International Limited analyzed them.  
\*\* Exposure vessels were glass aquaria equipped with shielded  
\*\* propeller-stirrers containing 20 liters of test media. The  
\*\* stirrers rotated at 2000 rpm. 10 fish were housed in each  
\*\* vessel and 20 fish were exposed at the experimental  
\*\* concentration. The experimental groups included a control  
\*\* and a group exposed to a concentration of 1000 mg/l. The  
\*\* exposure was conducted under a 16 hour/8 hour, light/dark  
\*\* photoperiod.  
\*\* The rainbow trout were supplied by Trafalgar Nurseries,  
\*\* Downton, Salisbury, U.K. The mean length and mean weight  
\*\* (sd) of the experimental fish were 4.8 cm (0.4 cm) and 1.33  
\*\* g (0.49 g), respectively. Fish were fed commercial trout  
\*\* pellets on a daily basis. Feeding was discontinued 24 hours  
\*\* prior to the initial exposure. The fish were laboratory  
\*\* acclimated for 4 days prior to a one week test condition  
\*\* acclimation. Biomass loading in the test chambers was 0.67  
\*\* g/l.  
\*\* Test water was tap water, dechlorinated through the addition  
\*\* of sodium thiosulfate. Exposures occurred at 14°C, a  
\*\* hardness of 50 mg/l as CaCO<sub>3</sub> and the D.O. level never

\*\* dropped below 10.0 mgO2/l. The pH of the control groups  
\*\* ranged from 7.6-7.7.  
F008 IUC4  
F020 3692  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. (1990)  
\*\* The Acute Toxicity of to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/3;  
\*\* Report No. AT301/023.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity of to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/3;  
\*\* Report No. AT301/023.  
F008 IUC4  
F020 3693  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. (1990)  
\*\* The Acute Toxicity of to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/7;  
\*\* Report No. AT301/027.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity of to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/7;  
\*\* Report No. AT301/027.  
F008 IUC4  
F020 3694  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/2;  
\*\* Report No. AT301/022.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/2;  
\*\* Report No. AT301/022.  
F008 IUC4  
F020 3695  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/55;

\*\* Report No. AT301/042.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/55;  
\*\* Report No. AT301/042.  
F008 IUC4  
F020 3696  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/65;  
\*\* Report No. AT301/044.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/65;  
\*\* Report No. AT301/044.  
F008 IUC4  
F020 3697  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/6;  
\*\* Report No. AT301/026.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/6;  
\*\* Report No. AT301/026.  
F008 IUC4  
F020 3698  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/1;  
\*\* Report No. AT301/021.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/1;  
\*\* Report No. AT301/021.  
F008 IUC4  
F020 3699  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE

F006 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/4;  
\*\* Report No. AT301/024.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/4;  
\*\* Report No. AT301/024.  
F008 IUC4  
F020 3700  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/56;  
\*\* Report No. AT301/043R.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/56;  
\*\* Report No. AT301/043R.  
F008 IUC4  
F020 3701  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/8;  
\*\* Report No. AT301/028.  
F007 BP International Limited. (1990)  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/8;  
\*\* Report No. AT301/028.  
F008 IUC4  
F020 3702  
EOR  
F002 40  
F010 4.1  
F004 15  
F005 RE  
F006 BP International Limited. 1990  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/5;  
\*\* Report No. AT301/025.  
F007 BP International Limited. 1990  
\*\* The Acute Toxicity to Rainbow Trout (Salmo gairdneri).  
\*\* Project No. 301/5;  
\*\* Report No. AT301/025.  
F008 IUC4  
F020 3703  
EOR  
F002 40

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F010 4.1
F004 15
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
** Fathead Minnow Acute Fish Toxicity Test.
** Study #101740.
F007 Exxon Biomedical Sciences, Inc. (1995)
** Fathead Minnow Acute Fish Toxicity Test.
** Study #101740.
F008 IUC4
F020 3704
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
** Fathead Minnow Acute Fish Toxicity Test.
** Study #198140.
F007 Exxon Biomedical Sciences, Inc. (1995)
** Fathead Minnow Acute Fish Toxicity Test.
** Study #198140.
F008 IUC4
F020 3705
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
** Fathead Minnow Acute Fish Toxicity Test.
** Study #198240.
F007 Exxon Biomedical Sciences, Inc. (1995)
** Fathead Minnow Acute Fish Toxicity Test.
** Study #198240.
F008 IUC4
F020 3706
EOR
F002 40
F010 4.1
F004 15
F005 RM
F006 Acute fish toxicity studies have been reported for 14 base
** oil samples (including the study summarized in full above).
** The results for all 14 samples are summarized in the table
** below.
**
** Result Reference
**
** Salmo gairdneri - semistatic test
F007 Acute fish toxicity studies have been reported for 14 base
** oil samples (including the study summarized in full above).
** The results for all 14 samples are summarized in the table
** below.
**
** Result Reference
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**      Salmo gairdneri - semistatic test
**      Distillates, solvent-refined heavy paraffinic (64741-88-4)
**
**      7-d LL0=1000 ppm dispersion      48
**      7-d LL0=1000 ppm dispersion      40
**      7-d LL0=1000 ppm dispersion      38
**      7-d LL0=1000 ppm dispersion      39
**      7-d LL0=1000 ppm dispersion      46
**      7-d LL0=1000 ppm dispersion      60
**
**      Distillates, solvent refined light paraffinic (64741-89-5)
**      96-h LL0=1000 ppm dispersion      42
**      7-d LL0=1000 ppm dispersion      45
**
**      Solvent deasphalted bright stock (64741-95-3)
**      96-h LL0=1000 ppm dispersion      47
**
**      Solvent refined residual oil (64742-01-4)
**      7-d LL0=1000 ppm dispersion      43
**      96-h LL0=1000 ppm dispersion      41
**
**      Pimephales promelas - static test
**      Distillates hydrotreated heavy paraffinic (64742-54-7)
**      96-h LL0=100 ppm WAF              78
**
**      Solvent dewaxed residual oil (64742-62-7)
**      96-h LL0=100 ppm WAF              79
**
**      Distillates solvent dewaxed heavy paraffinic (64742-65-0)
**      96-h LL0=100 ppm WAF              77
F008 IUC4
F020 3707
EOR
F002 40
F010 4.2
F004 1
F005 RE
F006 Shell Research Ltd. (1988)
**      Oils: Acute toxicity of four oils to Daphnia magna and
**      Gammarus pulex.
**      Report SBGR.88.075.
F007 Shell Research Ltd. (1988)
**      Oils: Acute toxicity of four oils to Daphnia magna and
**      Gammarus pulex.
**      Report SBGR.88.075.
F008 IUC4
F020 3708
EOR
F002 40
F010 4.2
F004 1
F005 RL
F006 Although test guidelines were not specified and the study
**      was not conducted under GLPs, it was a well-documented
**      study. Analytical monitoring of the oil concentration in the
**      WAFs was not performed. An oily film was visible on the
**      surface of

```

F007 Although test guidelines were not specified and the study  
\*\* was not conducted under GLPs, it was a well-documented  
\*\* study. Analytical monitoring of the oil concentration in the  
\*\* WAFs was not performed. An oily film was visible on the  
\*\* surface of some test solutions apparently as a carryover  
\*\* from the WAF preparations.

F008 IUC4  
F020 3709  
EOR  
F002 40  
F010 4.2  
F004 1  
F005 RS

F006 After 48 hrs no daphnid immobilization was found in any of  
\*\* the concentrations tested.  
\*\*  
\*\* The 48 hr EL0 was 10 g/l.  
\*\*  
\*\* Control survival was 100% after 48 hrs.

F007 After 48 hrs no daphnid immobilization was found in any of  
\*\* the concentrations tested.  
\*\*  
\*\* The 48 hr EL0 was 10 g/l.  
\*\*  
\*\* Control survival was 100% after 48 hrs.

F008 IUC4  
F020 3710  
EOR  
F002 40  
F010 4.2  
F004 1  
F005 TC

F006 Individual treatment concentrations were prepared as water  
\*\* accommodated fractions (WAF). Nominal loading rates in the  
\*\* definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control  
\*\* and dilution water was reconstituted hard water prepared by  
\*\* addi

F007 Individual treatment concentrations were prepared as water  
\*\* accommodated fractions (WAF). Nominal loading rates in the  
\*\* definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control  
\*\* and dilution water was reconstituted hard water prepared by  
\*\* adding salts to glass-distilled deionized water following  
\*\* EPA guidelines (hardness 174 mg/ml as CaCO3). Test substance  
\*\* was mixed in dilution water for 23 hrs. The mixtures were  
\*\* allowed to stand for 1 hr prior to siphoning off the aqueous  
\*\* phase for testing. Glass flasks (140 ml) were filled with  
\*\* each of the WAFs with 10 daphnids per vessel. The flasks  
\*\* were sealed with glass cover slip to minimize the loss of  
\*\* volatile components of the oil. Test daphnids were <24 hrs  
\*\* old and collected from cultures supplied by the testing  
\*\* laboratory that have been aged between 15 and 35 days. Two  
\*\* replicates per treatment and control were used. Black caps  
\*\* were placed over those flasks in which an oily film was  
\*\* visible on the surface of the test solution so the organisms  
\*\* would avoid the darkened zone and not be trapped in the  
\*\* film. Test temperature was 18 - 22 °C. Dissolved oxygen in  
\*\* the control and highest concentration was 8.8 to 9.1 mg/ml.

\*\* pH in the control and highest concentration was 7.7 - 8.0.  
 F008 IUC4  
 F020 3711  
 EOR  
 F002 40  
 F010 4.2  
 F004 2  
 F005 RE  
 F006 Shell Research Ltd. (1988)  
 \*\* Oils: Acute toxicity of four oils to *Daphnia magna* and  
 \*\* *Gammarus pulex*.  
 \*\* Report SBGR.88.075.  
 F007 Shell Research Ltd. (1988)  
 \*\* Oils: Acute toxicity of four oils to *Daphnia magna* and  
 \*\* *Gammarus pulex*.  
 \*\* Report SBGR.88.075.  
 F008 IUC4  
 F020 3712  
 EOR  
 F002 40  
 F010 4.2  
 F004 2  
 F005 RL  
 F006 Although test guidelines were not specified and the study  
 \*\* was not conducted under GLPs, it was a well-documented  
 \*\* study. Analytical monitoring of the oil concentration in the  
 \*\* WAFs was not performed.  
 F007 Although test guidelines were not specified and the study  
 \*\* was not conducted under GLPs, it was a well-documented  
 \*\* study. Analytical monitoring of the oil concentration in the  
 \*\* WAFs was not performed.  
 F008 IUC4  
 F020 3713  
 EOR  
 F002 40  
 F010 4.2  
 F004 2  
 F005 RS  
 F006 No dead organisms were found in any of the test vessels  
 \*\* after 96 hours. However, some organisms disappeared from all  
 \*\* treatments and control throughout the test. It was assumed  
 \*\* that these organisms were eaten by the remaining organisms.  
 \*\* The  
 F007 No dead organisms were found in any of the test vessels  
 \*\* after 96 hours. However, some organisms disappeared from all  
 \*\* treatments and control throughout the test. It was assumed  
 \*\* that these organisms were eaten by the remaining organisms.  
 \*\* The numbers of missing animals after 96 hours were 2, 1, 4,  
 \*\* 5, and 2 in the control, 0.01, 0.1, 1, and 10 g/l WAFs.  
 \*\* Since <50% of the organisms were missing in any  
 \*\* concentration, and even if these lost animals died as a  
 \*\* result of treatment, the 96-hr LL0 was 10 g/l.  
 F008 IUC4  
 F020 3714  
 EOR  
 F002 40  
 F010 4.2

F004 2  
 F005 TC  
 F006 Individual treatment concentrations were prepared as water  
 \*\* accommodated fractions (WAF). Nominal loading rates in the  
 \*\* definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control  
 \*\* and dilution water was laboratory mains tap water obtained  
 \*\* from  
 F007 Individual treatment concentrations were prepared as water  
 \*\* accommodated fractions (WAF). Nominal loading rates in the  
 \*\* definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control  
 \*\* and dilution water was laboratory mains tap water obtained  
 \*\* from bore holes, and passed through particle and activated  
 \*\* carbon filters (alkalinity 247 mg/ml as CaCO<sub>3</sub>, hardness 274  
 \*\* mg/ml as CaCO<sub>3</sub>, conductivity 492 mS/cm, pH 7.3). Test  
 \*\* substance was mixed in dilution water for 23 hrs. The  
 \*\* mixtures were allowed to stand for 1 hr prior to siphoning  
 \*\* off the aqueous phase for testing. Fresh WAFs were prepared  
 \*\* for each 24-hr renewal. Glass crystallizing dishes (350 ml)  
 \*\* were filled with 300 ml of each of the WAFs with 10  
 \*\* organisms per dish. Three replicates per treatment and  
 \*\* control were used. Test organisms were between 1 and 2 mm in  
 \*\* size and collected from a tributary of the River Len at  
 \*\* Hollingbourne, Kent, UK. Test temperature was 14 - 18.2 °C.  
 \*\* Dissolved oxygen in the control and highest concentration  
 \*\* was 7.8 to 9.9 mg/ml. pH in the control and highest  
 \*\* concentration was 6.8 - 8.5.  
 F008 IUC4  
 F020 3715  
 EOR  
 F002 40  
 F010 4.3  
 F004 1  
 F005 RE  
 F006 BP International Limited. (1990)  
 \*\* Assessment of the Algistatic Effect of \*\*\*\*\* to Scenedesmus  
 \*\* subspicatus. Project No. 301/74.  
 F007 BP International Limited. (1990)  
 \*\* Assessment of the Algistatic Effect of \*\*\*\*\* to Scenedesmus  
 \*\* subspicatus. Project No. 301/74.  
 F008 IUC4  
 F020 3716  
 EOR  
 F002 40  
 F010 4.3  
 F004 1  
 F005 RE  
 F006 BP International Limited. (1990)  
 \*\* Assessment of the Algistatic Effect of \*\*\*\*\* to Scenedesmus  
 \*\* subspicatus. Project No. 301/70.  
 F007 BP International Limited. (1990)  
 \*\* Assessment of the Algistatic Effect of \*\*\*\*\* to Scenedesmus  
 \*\* subspicatus. Project No. 301/70.  
 F008 IUC4  
 F020 3717  
 EOR  
 F002 40  
 F010 4.3

F004 1  
 F005 RE  
 F006 BP International Limited. (1990)  
 \*\* Assessment of the Algistatic Effect of \*\*\*\*\* to Scenedesmus  
 \*\* subspicatus. Project No. 301/72.  
 F007 BP International Limited. (1990)  
 \*\* Assessment of the Algistatic Effect of \*\*\*\*\* to Scenedesmus  
 \*\* subspicatus. Project No. 301/72.  
 F008 IUC4  
 F020 3718  
 EOR  
 F002 40  
 F010 4.3  
 F004 1  
 F005 RE  
 F006 BP International Limited. (1990)  
 \*\* Assessment of the Algistatic Effect of \*\*\*\*\* to Scenedesmus  
 \*\* subspicatus. Project No. 301/76.  
 F007 BP International Limited. (1990)  
 \*\* Assessment of the Algistatic Effect of \*\*\*\*\* to Scenedesmus  
 \*\* subspicatus. Project No. 301/76.  
 F008 IUC4  
 F020 3719  
 EOR  
 F002 40  
 F010 4.3  
 F004 1  
 F005 RL  
 F006 Only one concentration of the test substance was tested.  
 \*\* Results of chemical analyses of test substance  
 \*\* concentrations were not reported.  
 F007 Only one concentration of the test substance was tested.  
 \*\* Results of chemical analyses of test substance  
 \*\* concentrations were not reported.  
 F008 IUC4  
 F020 3720  
 EOR  
 F002 40  
 F010 4.3  
 F004 1  
 F005 RM  
 F006 Three other base oil samples have been tested for algal  
 \*\* toxicity.  
 \*\* The results for all three samples were similar to that  
 \*\* described above.  
 \*\* Samples tested at one concentration only were as follows:  
 \*\*  

** CAS No.	Result	Ref.
** 64741-88-4	96-h	

 F007 Three other base oil samples have been tested for algal  
 \*\* toxicity.  
 \*\* The results for all three samples were similar to that  
 \*\* described above.  
 \*\* Samples tested at one concentration only were as follows:  
 \*\*  

** CAS No.	Result	Ref.
** 64741-88-4	96-h LL0 = 50% WAF	34

\*\* 64741-89-5 96-h LL0 = 50% WAF 35  
 \*\* 64742-01-4 96-h LL0 = 50% WAF 37  
 F008 IUC4  
 F020 3721  
 EOR  
 F002 40  
 F010 4.3  
 F004 1  
 F005 RS  
 F006 No inhibition of growth or growth rate were measured at the  
 \*\* single test concentration of 50% WAF.  
 \*\* Since there were no observed effects during the study, the  
 \*\* 96-hour "No Observed Effect Concentration" (NOEC) was 50%  
 \*\* WAF.  
 \*\* The OECD guideline  
 F007 No inhibition of growth or growth rate were measured at the  
 \*\* single test concentration of 50% WAF.  
 \*\* Since there were no observed effects during the study, the  
 \*\* 96-hour "No Observed Effect Concentration" (NOEC) was 50%  
 \*\* WAF.  
 \*\* The OECD guideline criterion for cell growth in the control  
 \*\* group was met in this experiment.  
 F008 IUC4  
 F020 3722  
 EOR  
 F002 40  
 F010 4.3  
 F004 1  
 F005 TC  
 F006 Preparation of the Water Accommodated Fraction (WAF):2.0  
 \*\* grams of test material were placed on 2 Liters of culture  
 \*\* medium and stirred via magnetic stirrer for a period of 24  
 \*\* hours prior to the test. Culture medium was prepared  
 \*\* according to  
 F007 Preparation of the Water Accommodated Fraction (WAF):2.0  
 \*\* grams of test material were placed on 2 Liters of culture  
 \*\* medium and stirred via magnetic stirrer for a period of 24  
 \*\* hours prior to the test. Culture medium was prepared  
 \*\* according to the guideline formula. After the 24 hour  
 \*\* period, stirring was ceased for one hour prior to removing  
 \*\* the aqueous phase. The aqueous phase, representing 100%  
 \*\* WAF, was then combined with an equal volume of algal  
 \*\* suspension. The algal suspension consisted of Scenedesmus  
 \*\* cells taken from a culture in logarithmic growth phase and  
 \*\* diluted with growth medium to a cell density of  $3.70 \times 10^4$   
 \*\* cells/ml. The algal species Scenedesmus subspicatus utilized  
 \*\* in this study was supplied by the Culture Centre of Algae  
 \*\* and Protozoa (CCAP) c/o Institute of Freshwater Ecology,  
 \*\* Cumbria, U.K. Sterile culture medium was inoculated with  
 \*\* Scenedesmus and incubated under continuous illumination and  
 \*\* aeration at 21°C.  
 \*\* 10 ml samples of the 50% WAF were taken at times 0 and 96  
 \*\* hours. After adding 10 ml of  
 \*\* 1,1,2-trichlorotrifluoroethane, the samples were stored at  
 \*\* 4°C until analyzed. Analytical results were not reported.  
 \*\* 500 ml of the algal suspension were added to 500 ml of 100%  
 \*\* WAF to make the test solution. 100 ml of the test solution

\*\* was contained in a loosely stoppered 250 ml conical flask.  
\*\* All flasks were incubated and shaken at approximately 100  
\*\* rpm in an orbital shaker. 6 replicates of a single test  
\*\* concentration and 3 replicates of a control were examined in  
\*\* this study. The flasks were housed under a 24 hour light  
\*\* photoperiod at an intensity of approximately 7,000 lux and a  
\*\* constant temperature of 24°C. No aeration was supplied  
\*\* during the study, however, gas exchange and algal cell  
\*\* suspension was maintained by the orbital shaker. Samples  
\*\* were taken for the determination of algal growth every 24  
\*\* hours beginning at hour 0 and ending at hour 96.  
\*\* Absorbances were measured at 665 nm with a Jenway 610  
\*\* Spectrophotometer. At the initiation and completion of the  
\*\* experiment, the cell densities of the control cultures were  
\*\* determined through direct counting aided by a  
\*\* hemacytometer. The pH of all control and test flasks was  
\*\* taken at 0 and 96 hours. The pH at the beginning and end of  
\*\* the experiment in all groups ranged from 8.3 to 8.5 and 9.4  
\*\* to 9.9, respectively. The area under the curve and growth  
\*\* rate were taken as indices of algal growth and were  
\*\* calculated using the absorbance readings. Percent  
\*\* inhibition values were calculated for area under the curve  
\*\* and growth rate.

F008 IUC4

F020 3723

EOR

F002 40

F010 4.5.2

F004 1

F005 RE

F006 BP Oil Europe. (1995)

\*\* Daphnia magna Reproduction Test. SPL Project No. 692/038.

F007 BP Oil Europe. (1995)

\*\* Daphnia magna Reproduction Test. SPL Project No. 692/038.

F008 IUC4

F020 3724

EOR

F002 40

F010 4.5.2

F004 1

F005 RL

F006 The analytical results provided no definitive evidence of

\*\* stability of the test preparations. Only two test

\*\* concentrations were run.

F007 The analytical results provided no definitive evidence of

\*\* stability of the test preparations. Only two test

\*\* concentrations were run.

F008 IUC4

F020 3725

EOR

F002 40

F010 4.5.2

F004 1

F005 RS

F006 After 14 and 21 days of exposure, there were no

\*\* statistically significant differences between the control

\*\* group and the 10 and 1000 mg/ml WAF test groups in terms of

\*\* survival or reproduction (young produced per adult). In  
\*\* addition, there w

F007 After 14 and 21 days of exposure, there were no  
\*\* statistically significant differences between the control  
\*\* group and the 10 and 1000 mg/ml WAF test groups in terms of  
\*\* survival or reproduction (young produced per adult). In  
\*\* addition, there were no apparent effects on the F1  
\*\* generation produced during the test. The numbers of  
\*\* unhatched eggs and dead young were low in all treatment  
\*\* groups.  
\*\*

\*\* The NOEC for survival and reproduction was the maximum test  
\*\* concentration, 1000 mg/ml WAF.  
\*\*

\*\* The test met the validation criteria for 1) dissolved oxygen  
\*\* at least 60%, 2) pH deviation not greater than 0.3, 3)  
\*\* control mortality not greater than 20%, 4) first young  
\*\* (control group) within 9 days, 5) cumulative young per  
\*\* female (control group) at least 20 after 14 days and at  
\*\* least 40 after 21 days, and 6) number of broods per control  
\*\* group at least 3.

F008 IUC4  
F020 3726  
EOR  
F002 40  
F010 4.5.2  
F004 1  
F005 TC  
F006 Preparation of the WAF:  
\*\* 20 and 2000 mg of test material were each separately placed  
\*\* in 2 liters of reconstituted water (water hardness  
\*\* approximately 270 mg/ml as CaCO<sub>2</sub>) and stirred via magnetic  
\*\* stirrer for a period of 24 hours prior to the

F007 Preparation of the WAF:  
\*\* 20 and 2000 mg of test material were each separately placed  
\*\* in 2 liters of reconstituted water (water hardness  
\*\* approximately 270 mg/ml as CaCO<sub>2</sub>) and stirred via magnetic  
\*\* stirrer for a period of 24 hours prior to the test. After  
\*\* the 24-hour period, stirring was ceased for one hour prior  
\*\* to removing the aqueous phase.  
\*\*

\*\* Test Organism Culture:  
\*\* Adult *Daphnia magna* were maintained in polypropylene vessels  
\*\* containing approximately 2 liters of reconstituted water at  
\*\* a  
\*\* temperature of 21°C. The organisms were supplied by the  
\*\* Institut National de Recherche Appliquée (IRCHA) France.  
\*\* The lighting was held at 16:8 hour light:dark  
\*\* photoperiod. Gravid adults were isolated 24 hours prior to  
\*\* the initiation of the test, the young daphnids produced  
\*\* overnight were removed and utilized for testing.  
\*\*

\*\* Test Procedure:  
\*\* The aqueous phase of each WAF was removed and 400-ml  
\*\* aliquots were apportioned to five, 500-ml glass flasks. A  
\*\* similar number of control flasks containing reconstituted  
\*\* water also were prepared. The fifth flask from each group

\*\* was taken for Total Organic Carbon analysis of the exposure  
\*\* media. At the start of the test, 10 daphnids were placed  
\*\* within each test flask, and all flasks were covered to  
\*\* reduce evaporation. Each vessel received approximately 3.75  
\*\* x 10<sup>9</sup> cells/ml of a mixed unicellular algae culture as a  
\*\* daily feeding. Fresh WAFs were prepared on days 0, 2, 4, 7,  
\*\* 9, 11, 14, 16, and 18, and the adult daphnids were  
\*\* transferred from the old to the fresh solutions. The numbers  
\*\* of live and dead *Daphnia* of the parental generation were  
\*\* counted daily. At each test media renewal, *Daphnia* with  
\*\* eggs or young in the brood pouch, discarded unhatched eggs,  
\*\* and the number of live and dead filial *Daphnia* were counted.  
\*\*

\*\* Temperature was recorded daily for the duration of the  
\*\* experiment, while dissolved oxygen and pH were recorded  
\*\* prior to and after each media renewal. Measurements of TOC  
\*\* were made in the fresh and old test solutions 3 times a week  
\*\* over 21 days. Dissolved oxygen in the control, 10, and 1000  
\*\* mg/ml WAF groups ranged from 7.9 to 8.3, from 7.9 to 8.3,  
\*\* and from 7.8 to 8.3, respectively. Water pH in the control,  
\*\* 10, and 1000 mg/ml WAF groups ranged from 7.7 to 7.8, from  
\*\* 7.7 to 7.8, and from 7.7 to 7.8, respectively. The  
\*\* temperature within all test groups remained constant at 21.0  
\*\* °C. The results of the TOC analysis did not demonstrate a  
\*\* direct relationship with WAF concentration, and in many  
\*\* cases the TOC of the control water was higher than that of  
\*\* the test groups. The TOC in the old media tended to be  
\*\* higher than fresh solutions.

F008 IUC4

F020 3727

EOR

F002 40

F010 4.5.2

F004 12

F005 RE

F006 BP Oil Europe. (1995)

\*\* *Daphnia magna* Reproduction Test. SPL Project No. 692/037.

F007 BP Oil Europe. (1995)

\*\* *Daphnia magna* Reproduction Test. SPL Project No. 692/037.

F008 IUC4

F020 3728

EOR

F002 40

F010 4.5.2

F004 12

F005 RE

F006 BP Oil Europe. (1995)

\*\* *Daphnia magna* Reproduction Test. SPL Project No. 692/039.

F007 BP Oil Europe. (1995)

\*\* *Daphnia magna* Reproduction Test. SPL Project No. 692/039.

F008 IUC4

F020 3729

EOR

F002 40

F010 4.5.2

F004 12

F005 RE  
F006 BP Oil Europe. (1995)  
\*\* Daphnia magna Reproduction Test. SPL Project No. 692/040.  
F007 BP Oil Europe. (1995)  
\*\* Daphnia magna Reproduction Test. SPL Project No. 692/040.  
F008 IUC4  
F020 3730  
EOR  
F002 40  
F010 4.5.2  
F004 12  
F005 RE  
F006 BP Oil Europe. (1995)  
\*\* Daphnia magna Reproduction Test. SPL Project No. 692/041.  
F007 BP Oil Europe. (1995)  
\*\* Daphnia magna Reproduction Test. SPL Project No. 692/041.  
F008 IUC4  
F020 3731  
EOR  
F002 40  
F010 4.5.2  
F004 12  
F005 RE  
F006 BP Oil Europe. (1995)  
\*\* Daphnia magna Reproduction Test. SPL Project No. 692/042.  
F007 BP Oil Europe. (1995)  
\*\* Daphnia magna Reproduction Test. SPL Project No. 692/042.  
F008 IUC4  
F020 3732  
EOR  
F002 40  
F010 4.5.2  
F004 12  
F005 RE  
F006 BP Oil Europe. (1995)  
\*\* Daphnia magna Reproduction Test. SPL Project No. 692/036.  
F007 BP Oil Europe. (1995)  
\*\* Daphnia magna Reproduction Test. SPL Project No. 692/036.  
F008 IUC4  
F020 3733  
EOR  
F002 40  
F010 4.5.2  
F004 12  
F005 RE  
F006 Shell Research Limited. (1994)  
\*\* Chronic toxicity of water-accommodated fractions to Daphnia  
\*\* magna. Experiment #5922.  
F007 Shell Research Limited. (1994)  
\*\* Chronic toxicity of water-accommodated fractions to Daphnia  
\*\* magna. Experiment #5922.  
F008 IUC4  
F020 3734  
EOR  
F002 40  
F010 4.5.2  
F004 12

F005 RE

F006 Shell Research Limited. (1995)

\*\* Chronic toxicity of water accommodated fractions to Daphnia

\*\* magna. Experiment #6215.

F007 Shell Research Limited. (1995)

\*\* Chronic toxicity of water accommodated fractions to Daphnia

\*\* magna. Experiment #6215.

F008 IUC4

F020 3735

EOB

F002 40

F010 4.5.2

F004 12

F005 RM

F006 In addition to the study described above studies have been

\*\* reported for ten further base oil samples in 21 day studies

\*\* with D. magna. In each case OECD guideline 202 part 2 was

\*\* used as the method.

\*\* The results are summarized below:

\*\*

\*\* CAS No.

F007 In addition to the study described above studies have been

\*\* reported for ten further base oil samples in 21 day studies

\*\* with D. magna. In each case OECD guideline 202 part 2 was

\*\* used as the method.

\*\* The results are summarized below:

\*\*

CAS No.	Result	Reference
64741-88-4	21-d LL0 = 1000 mg/l WAF	63
64741-88-4	21-d LL0 = 1000 mg/l WAF	64
64741-88-4	21-d LL0 = 1000 mg/l WAF	100
64741-89-5	21-d LL0 = 1000 mg/l WAF	67
64741-89-5	21-d LL0 = 1000 mg/l WAF	61
64741-95-3	21-d LL0 = 1000 mg/l WAF	66
64742-01-4	21-d LL0 = 1000 mg/l WAF	65
64742-53-6	21-d LL0 = 10 mg/l WAF	101
64742-55-8	21-d LL0 = 1000 mg/l WAF	100
64742-65-0	21-d LL0 = 1000 mg/l WAF	100

\*\*

\*\* Of the reported chronic toxicity studies, no chronic effects

\*\* were observed below 1 mg/l. For all but two studies, no

\*\* chronic toxicity was seen at the highest addition of the

\*\* various base oils tested, which ranged from 1000 to 5000

\*\* mg/l.

F008 IUC4

F020 3736

EOB

F002 40

F010 5.1.1

F004 1

F005 ME

F006 A single dose of undiluted test material (5g/kg) was

\*\* administered orally to 5 male and 5 female fasted rats.

\*\* Food and water was made available ad-lib immediately after

\*\* dosing.

\*\* The animals were observed for clinical signs and mortality

\*\* at h

F007 A single dose of undiluted test material (5g/kg) was  
\*\* administered orally to 5 male and 5 female fasted rats.  
\*\* Food and water was made available ad-lib immediately after  
\*\* dosing.  
\*\* The animals were observed for clinical signs and mortality  
\*\* at hourly intervals for the first 6 hours post dosing and  
\*\* twice daily thereafter. Body weights were recorded prior to  
\*\* fasting, prior to dosing and at 7 and 14 days post dosing.  
\*\* At 14 days, all surviving animals were killed and subjected  
\*\* to a gross necropsy examination.

F008 IUC4  
F020 3737  
EOR  
F002 40  
F010 5.1.1  
F004 1  
F005 RE  
F006 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 84

F007 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 84-01 Light paraffinic distillate CAS 64741-50-0  
\*\* API Med. Res. Publ.: 33-30595

F008 IUC4  
F009 11-09-2010  
F020 3738  
EOR  
F002 40  
F010 5.1.1  
F004 1  
F005 RS  
F006 There were no deaths during the study and growth rates were  
\*\* unaffected by dosing. Clinical signs that occurred during  
\*\* the first 3 days included: hypoactivity, diarrhea and a  
\*\* yellow-stained anal area. All animals returned to normal by  
\*\* day

F007 There were no deaths during the study and growth rates were  
\*\* unaffected by dosing. Clinical signs that occurred during  
\*\* the first 3 days included: hypoactivity, diarrhea and a  
\*\* yellow-stained anal area. All animals returned to normal by  
\*\* day 14. At gross necropsy, there were no visible lesions.

F008 IUC31  
F020 3739  
EOR  
F002 40  
F010 5.1.1  
F004 2  
F005 ME

F006 A single dose of undiluted test material (5g/kg) was  
\*\* administered orally to 5 male and 5 female fasted rats.  
\*\* Food and water was made available ad-lib immediately after  
\*\* dosing.  
\*\* The animals were observed for clinical signs and mortality  
\*\* at h  
F007 A single dose of undiluted test material (5g/kg) was  
\*\* administered orally to 5 male and 5 female fasted rats.  
\*\* Food and water was made available ad-lib immediately after  
\*\* dosing.  
\*\* The animals were observed for clinical signs and mortality  
\*\* at hourly intervals for the first 6 hours post dosing and  
\*\* twice daily thereafter. Body weights were recorded prior to  
\*\* fasting, prior to dosing and at 7 and 14 days post dosing.  
\*\* At 14 days, all surviving animals were killed and subjected  
\*\* to a gross necropsy examination.  
F008 IUC31  
F020 3740  
EOR  
F002 40  
F010 5.1.1  
F004 2  
F005 RE  
F006 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 83  
F007 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 83-12 Hydrotreated light naphthenic distillate CAS  
\*\* 64742-53-6  
\*\* API Med. Res. Publ.: 33-30592  
F008 IUC4  
F009 11-09-2010  
F020 3741  
EOR  
F002 40  
F010 5.1.1  
F004 2  
F005 RS  
F006 There were no deaths during the study.  
\*\* Clinical signs observed included: hypoactivity,  
\*\* yellow-stained anal area, hair loss in the urogenital region  
\*\* and swollen hind paws.  
\*\* All animals returned to normal by day 3 and had gained  
\*\* weight by day  
F007 There were no deaths during the study.  
\*\* Clinical signs observed included: hypoactivity,  
\*\* yellow-stained anal area, hair loss in the urogenital region  
\*\* and swollen hind paws.

\*\* All animals returned to normal by day 3 and had gained  
\*\* weight by day 7.  
\*\* At necropsy, there were no visible lesions except in one  
\*\* female in which the spleen was cystic, mottled red and tan  
\*\* and had a rough surface. In this animal the pancreas adhered  
\*\* to the entire surface of the spleen.

F008 IUC31  
F020 3742  
EOR  
F002 40  
F010 5.1.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F008 IUC31  
F020 3743  
EOR  
F002 40  
F010 5.1.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F008 IUC31  
F020 3744  
EOR  
F002 40  
F010 5.1.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F008 IUC31  
F020 3745  
EOR  
F002 40  
F010 5.1.1  
F004 3

F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F008 IUC31  
F020 3746  
EOR  
F002 40  
F010 5.1.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F008 IUC31  
F020 3747  
EOR  
F002 40  
F010 5.1.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066  
F008 IUC31  
F020 3748  
EOR  
F002 40  
F010 5.1.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33068  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33068  
F008 IUC31  
F020 3749  
EOR

F002 40  
 F010 5.1.1  
 F004 3  
 F005 RE  
 F006 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in guinea pigs  
 \*\* API sa  
 F007 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in guinea pigs  
 \*\* API sample 83-15 hydrotreated heavy naphthenic distillate  
 \*\* (CAS 64742-52-5)  
 \*\* API Health Environ. Sci. Dep. Rep. 33-32639  
 F008 IUC31  
 F020 3750  
 EOR  
 F002 40  
 F010 5.1.1  
 F004 3  
 F005 RE  
 F006 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F007 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F008 IUC31  
 F020 3751  
 EOR  
 F002 40  
 F010 5.1.1  
 F004 3  
 F005 RM  
 F006 CONCAWE summarized the data available on the acute oral  
 \*\* toxicity of lubricating oil base stocks. The data are shown  
 \*\* in the following table.  
 \*\*  

** Paraffinic distillates	CAS No.	Oral LD50	API
** Solvent dewaxed, light	(g/kg)	Report No.	

 F007 CONCAWE summarized the data available on the acute oral  
 \*\* toxicity of lubricating oil base stocks. The data are shown  
 \*\* in the following table.  
 \*\*  

** Paraffinic distillates	CAS No.	Oral LD50	API
** Solvent dewaxed, light	(g/kg)	Report No.	
** API 78-9	64742-56-9	>5	29-33104

**	Solvent dewaxed, heavy			
**	API 78-10*	64742-56-0	>5	29-33105
**	API 79-3	64742-65-0	>5	29-33067
**	API 79-4	64742-65-0	>5	29-33066
**	API 79-5	64742-65-0	>5	29-33068
**				
**	White mineral oil			
**	Tufflo 6056*		>5	39-31651
**				
**	Naphthenic distillates			
**				
**	Solvent refined, light			
**	API 78-5	64741-97-5	>5	29-33106
**	Solvent refined, heavy			
**	API 79-1	64741-96-4	>5	29-33065
**	Hydrotreated, heavy			
**	API 83-15	64742-52-5	>5	33-32639
**				
**				
**				

\* Although these materials are not included in the HPV Lubricating base stocks category, they are similar to other materials in the category and provide supportive information.

F008 IUC31

F020 3752

EOR

F002 40

F010 5.1.2

F004 1

F005 ME

F006 A group of 5 male and 5 female rats were exposed for 4 hours

\*\* to an aerosol of the test material at a target concentration

\*\* of 5 mg/l. Four additional groups of rats were then exposed

\*\* for 4 hours to target aerosol concentrations of 1, 1.5, 2

F007 A group of 5 male and 5 female rats were exposed for 4 hours

\*\* to an aerosol of the test material at a target concentration

\*\* of 5 mg/l. Four additional groups of rats were then exposed

\*\* for 4 hours to target aerosol concentrations of 1, 1.5, 2.5

\*\* and 3.5 mg/l. A control group exposed, in the chamber, to

\*\* air only was also included.

\*\* Animals were observed continuously during the first hour of

\*\* exposure, hourly for the remainder of the exposure and once

\*\* daily for the 14-day post exposure period. Mortalities were

\*\* recorded and body weights were measured prior to exposure

\*\* and again 7 and 14 days after exposure. On the 14th day

\*\* post-exposure, necropsies were performed on all surviving

\*\* animals. For all animals, including animals found dead, the

\*\* lungs and any other abnormal tissues were removed and fixed

\*\* for subsequent histopathological examination.

F008 IUC31

F020 3753

EOR

F002 40

F010 5.1.2

F004 1

F005 RE

F006 American Petroleum Institute (1987)

\*\* Acute inhalation toxicity evaluation of a petroleum derived

\*\* hydrocarbon in rats. API 83-12 Hydrotreated light naphthenic

\*\* distillate CAS 64742-53-6

\*\* API HESD Publ. 34-32775

F007 American Petroleum Institute (1987)

\*\* Acute inhalation toxicity evaluation of a petroleum derived

\*\* hydrocarbon in rats. API 83-12 Hydrotreated light naphthenic

\*\* distillate CAS 64742-53-6

\*\* API HESD Publ. 34-32775

F008 IUC4

F009 11-09-2010

F020 3754

EOR

F002 40

F010 5.1.2

F004 1

F005 RS

F006 Actual exposure concentrations and mortalities were as

\*\* follows:

\*\*

Target level (mg/l)	Actual concentration mg/l ±SD		Mortality Male Female	
0	0.02	0.01	0/5	0/5
1.0	1.04	0.1	1/5	1/5
1.5	1.51	0.15	0/5	0/5
2.5	2.37	0.31	3/5	3/5
3.5	3.			

F007 Actual exposure concentrations and mortalities were as

\*\* follows:

\*\*

Target level (mg/l)	Actual concentration mg/l ±SD		Mortality Male Female	
0	0.02	0.01	0/5	0/5
1.0	1.04	0.1	1/5	1/5
1.5	1.51	0.15	0/5	0/5
2.5	2.37	0.31	3/5	3/5
3.5	3.49	0.36	5/5	5/5
5.0	5.05	0.18	5/5	5/5

\*\* Particle size measurements confirmed that mass median

\*\* aerodynamic diameter and geometric standard deviation values

\*\* were in the ranges 1.7 to 2.5 µm and 1.5 to 1.61

\*\* respectively. These measurements confirm that the particles

\*\* were within the respirable range.

\*\* The LC50 for combined sexes was estimated to be 2.18 with

\*\* 95% confidence limits of 1.80 to 2.55 mg/l.

\*\*

\*\* Body weight differences did not show a consistent dose

\*\* related pattern.

\*\*

\*\* At the highest concentration, the animals were obscured by a

\*\* dense aerosol and observations could not be made during the

\*\* exposure period. In other groups, there was a decreased

\*\* activity, wet inguinal area, eyes partially closed, wet

\*\* coat, loose stool and oily coat during exposure.

\*\* During the first week post-exposure, similar signs were  
\*\* observed as well as signs of poor condition, respiratory  
\*\* distress and some deaths occurred. During test week 2, most  
\*\* survivors were considered to be of normal appearance. The  
\*\* signs that were observed occurred in a dose related manner.

\*\* At gross necropsy, dark red lungs were described for some  
\*\* animals. The incidence is shown below.

Dose group	Male	Female
0	0/5	0/5
1.0	1/5	1/5
1.5	0/5	0/5
2.5	3/5	3/5
3.5	5/5	5/5
5.0	5/5	5/5

\*\* At histology, affected animals exhibited diffuse pulmonary  
\*\* congestion and perivascular edema that were mostly moderate  
\*\* or marked in degree. Less consistently spotty alveolar edema  
\*\* was also seen. There was widespread damage to alveolar walls  
\*\* resulting in fibroncrotic debris resembling hyaline  
\*\* membranes in more marked cases and extravasation of RBCs and  
\*\* PMNs. Necrosis and inflammation were seen in the walls of  
\*\* small blood vessels and there was spotty epithelial necrosis  
\*\* in small bronchioles, but the most severe damage seemed to  
\*\* be centroacinar. The larger airways were relatively  
\*\* unaffected.

\*\* None of the surviving animals exhibited the above acute  
\*\* changes. However, most of the surviving animals exposed to  
\*\* 2.5 or 1.0 mg/l and above exhibited chronic inflammatory  
\*\* changes that were not seen in the controls and only  
\*\* occasionally in animals exposed at the 1.5 mg/l level, and  
\*\* then to a lesser degree of severity.  
\*\* Other findings were considered sporadic or unrelated to  
\*\* exposure to the test material.

F008 IUC31

F020 3755

EOR

F002 40

F010 5.1.2

F004 1

F005 TC

F006 Whole body exposures were carried out in stainless steel and  
\*\* glass chambers of 0.25 cubic meter volume.

\*\* Aerosols were generated using a nebulizer.

\*\* Concentrations of test material in the exposure chambers  
\*\* were determined gravimetrically by c

F007 Whole body exposures were carried out in stainless steel and  
\*\* glass chambers of 0.25 cubic meter volume.

\*\* Aerosols were generated using a nebulizer.

\*\* Concentrations of test material in the exposure chambers  
\*\* were determined gravimetrically by collection of the aerosol  
\*\* on filters. Analytical samples were taken at least once per  
\*\* hour during the exposure period. Particle size  
\*\* determinations were also carried out.

F008 IUC31  
 F020 3756  
 EOR  
 F002 40  
 F010 5.1.2  
 F004 2  
 F005 RE  
 F006 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F007 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F008 IUC31  
 F020 3757  
 EOR  
 F002 40  
 F010 5.1.2  
 F004 2  
 F005 RE  
 F006 Whitman, F. T., Freeman, J. J., Infurna, R. N. and Phillips,  
 \*\* R. D. (1989)  
 \*\* Evaluation of the acute and subacute inhalation toxicity of  
 \*\* lubricating oil mists  
 \*\* The toxicologist Vol. 9., p 143  
 F007 Whitman, F. T., Freeman, J. J., Infurna, R. N. and Phillips,  
 \*\* R. D. (1989)  
 \*\* Evaluation of the acute and subacute inhalation toxicity of  
 \*\* lubricating oil mists  
 \*\* The toxicologist Vol. 9., p 143  
 F008 IUC31  
 F020 3758  
 EOR  
 F002 40  
 F010 5.1.2  
 F004 2  
 F005 RM  
 F006 CONCAWE summarized the data available on the acute  
 \*\* inhalation toxicity of lubricating oil mists in 4 hour  
 \*\* exposure studies in rats.  
 \*\* The data (Original source Whitman et al, 1989) on 3  
 \*\* paraffinic distillates are shown in the following tabl  
 F007 CONCAWE summarized the data available on the acute  
 \*\* inhalation toxicity of lubricating oil mists in 4 hour  
 \*\* exposure studies in rats.  
 \*\* The data (Original source Whitman et al, 1989) on 3  
 \*\* paraffinic distillates are shown in the following table.  
 \*\*  
 \*\* Inhalation LC50  
 \*\* (mg/l)  
 \*\* Paraffinic distillates  
 \*\* Solvent extracted, dewaxed >4  
 \*\* Solvent extracted, dewaxed, hydrotreated >4  
 \*\* Solvent dewaxed, light >4  
 F008 IUC31

F020 3759  
EOR  
F002 40  
F010 5.1.3  
F004 1  
F005 ME  
F006 Undiluted test material was applied as a single dose (2g/kg)  
\*\* to the shorn, abraded skin of 4 male and 4 female rabbits.  
\*\* The treated site was covered with an occlusive dressing for  
\*\* 24 hours. After removal of the dressing, the skin was wipe  
F007 Undiluted test material was applied as a single dose (2g/kg)  
\*\* to the shorn, abraded skin of 4 male and 4 female rabbits.  
\*\* The treated site was covered with an occlusive dressing for  
\*\* 24 hours. After removal of the dressing, the skin was wiped  
\*\* with a wet towel to remove residual test material. The  
\*\* rabbits were observed for clinical signs and mortality  
\*\* hourly for the first 6 hours, then daily for dermal  
\*\* irritation and twice daily for clinical signs and mortality.  
\*\* Observation was carried out for a 14-day post treatment  
\*\* period. Body weights were recorded prior to administration  
\*\* of the test material, again 7 days post dosing and at study  
\*\* termination (14 days). At termination, all surviving animals  
\*\* were killed and subjected to a gross necropsy examination.  
F008 IUC31  
F020 3760  
EOR  
F002 40  
F010 5.1.3  
F004 1  
F005 RE  
F006 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 84  
F007 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 84-01 Light paraffinic distillate CAS 64741-50-0  
\*\* API Med. Res. Publ.: 33-30595  
F008 IUC4  
F009 11-09-2010  
F020 3761  
EOR  
F002 40  
F010 5.1.3  
F004 1  
F005 RS  
F006 There were no mortalities during the study.  
\*\* With the exception of skin irritation, there were no  
\*\* clinical signs of toxicity except that on day 4 soft stool  
\*\* was observed in 1 male and 3 female animals.

\*\* Dermal irritation ranged from slight to  
 F007 There were no mortalities during the study.  
 \*\* With the exception of skin irritation, there were no  
 \*\* clinical signs of toxicity except that on day 4 soft stool  
 \*\* was observed in 1 male and 3 female animals.  
 \*\* Dermal irritation ranged from slight to severe for erythema  
 \*\* and edema, from slight to marked for fissuring and slight to  
 \*\* moderate for atonia and desquamation. Slight coriaceousness  
 \*\* was also observed.  
 \*\* Body weight losses were recorded for 2 male and 3 female  
 \*\* animals at day 7. One male was less than starting weight on  
 \*\* both day 7 and day 14.  
 F008 IUC31  
 F020 3762  
 EOR  
 F002 40  
 F010 5.1.3  
 F004 2  
 F005 ME  
 F006 Undiluted test material was applied as a single dose (2g/kg)  
 \*\* to the shorn, abraded skin of 4 male and 4 female rabbits.  
 \*\* The treated site was covered with an occlusive dressing for  
 \*\* 24 hours. After dressing removal, the skin was wiped with  
 F007 Undiluted test material was applied as a single dose (2g/kg)  
 \*\* to the shorn, abraded skin of 4 male and 4 female rabbits.  
 \*\* The treated site was covered with an occlusive dressing for  
 \*\* 24 hours. After dressing removal, the skin was wiped with a  
 \*\* wet towel to remove residual test material. The rabbits  
 \*\* were observed for clinical signs and mortality hourly for  
 \*\* the first 6 hours, then daily for dermal irritation and  
 \*\* twice daily for clinical signs and mortality. Observation  
 \*\* was carried out for a 14-day post treatment period. Body  
 \*\* weights were recorded prior to administration of the test  
 \*\* material, again 7 days post dosing and at study termination  
 \*\* (14 days). At termination, all surviving animals were killed  
 \*\* and subjected to a gross necropsy examination.  
 F008 IUC31  
 F020 3763  
 EOR  
 F002 40  
 F010 5.1.3  
 F004 2  
 F005 RE  
 F006 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in Guinea pigs  
 \*\* API 83  
 F007 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in Guinea pigs  
 \*\* API 83-12 Hydrotreated light naphthenic distillate CAS

\*\* 64742-53-6  
\*\* API Med. Res. Publ.: 33-30592  
F008 IUC4  
F009 11-09-2010  
F020 3764  
EOR  
F002 40  
F010 5.1.3  
F004 2  
F005 RS  
F006 There were no deaths during the study.  
\*\* The only clinical observation with the exception of skin  
\*\* irritation was soft stool in all animals. This was observed  
\*\* 3 hours after dosing and returned to normal by day 2.  
\*\* Skin irritation was observed i  
F007 There were no deaths during the study.  
\*\* The only clinical observation with the exception of skin  
\*\* irritation was soft stool in all animals. This was observed  
\*\* 3 hours after dosing and returned to normal by day 2.  
\*\* Skin irritation was observed in all animals and ranged from  
\*\* slight to severe for erythema and edema, from slight to  
\*\* marked for atonia, desquamation and fissuring and from  
\*\* slight to moderate for coriaceousness. Other dermal  
\*\* irritation seen included blanching and subcutaneous  
\*\* hemorrhage.  
\*\* All animals had gained weight by the end of the study.  
\*\* At necropsy, except for the skin lesions no other visible  
\*\* lesions were recorded.  
F008 IUC31  
F020 3765  
EOR  
F002 40  
F010 5.1.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F008 IUC31  
F020 3766  
EOR  
F002 40  
F010 5.1.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)

\*\* API Med. Res. Publ. 29-33106  
F008 IUC31  
F020 3767  
EOR  
F002 40  
F010 5.1.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F008 IUC31  
F020 3768  
EOR  
F002 40  
F010 5.1.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F008 IUC31  
F020 3769  
EOR  
F002 40  
F010 5.1.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F008 IUC31  
F020 3770  
EOR  
F002 40  
F010 5.1.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066

F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066  
F008 IUC31  
F020 3771  
EOR  
F002 40  
F010 5.1.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33068  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33068  
F008 IUC31  
F020 3772  
EOR  
F002 40  
F010 5.1.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in guinea pigs  
\*\* API sa  
F007 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in guinea pigs  
\*\* API sample 83-15 hydrotreated heavy naphthenic distillate  
\*\* (CAS 64742-52-5)  
\*\* API Health Environ. Sci. Dep. Rep. 33-32639  
F008 IUC31  
F020 3773  
EOR  
F002 40  
F010 5.1.3  
F004 3  
F005 RE  
F006 CONCAWE (1997)  
\*\* Lubricating oil basestocks  
\*\* Product dossier No. 97/108  
\*\* CONCAWE, Brussels  
F007 CONCAWE (1997)  
\*\* Lubricating oil basestocks  
\*\* Product dossier No. 97/108  
\*\* CONCAWE, Brussels

F008 IUC31

F020 3774

EOR

F002 40

F010 5.1.3

F004 3

F005 RM

F006 CONCAWE summarized the data available on the acute dermal

\*\* toxicity of lubricating oil base stocks in rabbits. The

\*\* data are shown in the following table.

	Dermal	API
	LD50	Report No.
	(g/kg)	
** Paraffinic distillates	CAS	

F007 CONCAWE summarized the data available on the acute dermal

\*\* toxicity of lubricating oil base stocks in rabbits. The

\*\* data are shown in the following table.

	Dermal	API
	LD50	Report No.
	(g/kg)	
** Paraffinic distillates	CAS No.	
** Solvent dewaxed, light		
** API 78-9	64742-56-9 >5	29-33104
** Solvent dewaxed, heavy		
** API 78-10*	64742-56-0 >5	29-33105
** API 79-3	64742-65-0 >5	29-33067
** API 79-4	64742-65-0 >5	29-33066
** API 79-5	64742-65-0 >5	29-33068

\*\*

\*\* Naphthenic distillates

\*\*

** Solvent refined, light		
** API 78-5	64741-97-5 >5	29-33106
** Solvent refined, heavy		
** API 79-1	64741-96-4 >5	29-33065
** Hydrotreated, heavy		
** API 83-15	64742-52-5 >2	33-32639

\*\*

\*\* \* Although this material is not included in the HPV Lubricating  
base

\* stocks category, it is similar to other materials in the category and  
\* provides supportive information.

F008 IUC31

F020 3775

EOR

F002 40

F010 5.11

F004 1

F005 ME

F006 Groups of 10 presumed-pregnant rats were distributed into

\*\* the

\*\* following groups:

\*\*

Group	Dose level	Gestation days of
	(mg/kg/day)	administration

\*\*

```

**      1      0 (remote control)      0-19
**      2      0 (proximate control)    0-19
**

```

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F007 Groups of 10 presumed-pregnant rats were distributed into
** the
** following groups:
**

```

Group	Dose level (mg/kg/day)	Gestation days of administration
1	0 (remote control)	0-19
2	0 (proximate control)	0-19
3	30	0-19
4	125	0-19
5	500	0-19
6	1000	0-19
7*	500 (bioavailability)	10-12

```

**      * Group size was 5 at start but increased to 8 after study
**      initiation.
**

```

```

**      The test material was applied daily to the shorn dorsal skin
**      at the dose levels shown above and for the duration
**      indicated. The rats were fitted with collars to prevent oral
**      ingestion of the applied material.

```

```

**      Since it was believed that inhalation of test material
**      could be a confounding factor a second group of controls
**      (remote controls) were housed in an area in which they could
**      not inhale gasoil that had been applied to other animals.
**

```

```

**      Observations were made daily for clinical signs and body
**      weights and food consumption were recorded regularly
**      throughout the study.
**

```

```

**      Each female was sacrificed on day 20 of presumed gestation
**      and the thoracic and abdominal cavities were examined
**      grossly.

```

```

**      The thymus and liver were removed from each animal and
**      weighed and then preserved in formalin but not examined
**      further.

```

```

**      The uterus and ovaries were removed and examined grossly.
**      The number of corpora lutea per ovary for each rat was
**      recorded. The ovaries of non-pregnant females were examined
**      and then discarded. Uterus weights were also determined.
**      The uterine contents of each pregnant rat were exposed and a
**      record made of the number and location of all implantations.
**      At necropsy, blood samples were taken from all the animals
**      and a range of clinical chemical measurements were made.
**      Fetuses were examined and half were preserved for
**      examination of soft tissue abnormalities, the remainder
**      being differentially stained for skeletal examination.

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F008 IUC31

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F020 3776

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EOR

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F002 40

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```

F010 5.11

```

```

F004 1

```

F005 RE

F006 Mobil (undated)

\*\* Developmental toxicity screen in rats exposed dermally to

\*\* heavy vacuum gas oil (HVGO)

\*\* Study No. 61801 Final report

F007 Mobil (undated)

\*\* Developmental toxicity screen in rats exposed dermally to

\*\* heavy vacuum gas oil (HVGO)

\*\* Study No. 61801 Final report

F008 IUC31

F020 3777

EOR

F002 40

F010 5.11

F004 1

F005 RL

F006 The report evaluated was incomplete but nevertheless was

\*\* sufficient to identify the relevant effects of exposure to

\*\* the test material.

F007 The report evaluated was incomplete but nevertheless was

\*\* sufficient to identify the relevant effects of exposure to

\*\* the test material.

F008 IUC31

F020 3778

EOR

F002 40

F010 5.11

F004 1

F005 RS

F006 Parental animals.

\*\*

\*\* There were no clinical signs attributable to exposure to

\*\* HVGO other than in the highest dose group in which 2 rats

\*\* had a red vaginal discharge, one animal was pale in color

\*\* and six had decreased stool. The latter observat

F007 Parental animals.

\*\*

\*\* There were no clinical signs attributable to exposure to

\*\* HVGO other than in the highest dose group in which 2 rats

\*\* had a red vaginal discharge, one animal was pale in color

\*\* and six had decreased stool. The latter observation was

\*\* probably associated with a smaller food consumption in this

\*\* group. Although food consumption was generally also less

\*\* than controls in the 500 mg/kg/day group there was no

\*\* associated body weight decrease.

\*\* At doses in excess of 125 mg/kg/day there was a decrease in

\*\* mean body weights which reflected the decreased litter sizes

\*\* for this group.

\*\* The only dose-related finding at gross necropsy was a pale

\*\* appearance of lungs in a few animals. 4 animals were

\*\* affected at the highest dose and only one in the 500

\*\* mg/kg/day group.

\*\* Mean thymus weights of animals in the highest dose group

\*\* were approximately half those of the control groups.

\*\* Although absolute liver weights were unaffected by exposure

\*\* to HVGO, mean relative liver weights were increased

\*\* (approximately 15%) in groups exposed to doses greater than

\*\* 125 mg/kg/day.

\*\*

\*\* Observations of Dams at Caesarean section.

\*\*

\*\* Parameters with treatment-related effects are shown below.

\*\*

\*\* Dose group (mg/kg/day)

\*\*

\*\* 0 (R) 0 (P) 30 125 500 1000

\*\* Pregnant females

\*\* 9 10 10 8 10 9

\*\* Dams with viable fetuses

\*\* 9 10 10 8 10 6

\*\* Dams with all resorptions

\*\* 0 0 0 0 0 3

\*\* Mean litter size of viable fetuses

\*\* 13.9 14 13.8 14.4 10 5.8

\*\* Resorptions

\*\* Mean 1.1 0.6 1.1 1.1 5.6 9.9

\*\* % Dams with resorptions

\*\* 56 50 70 63 100 100

\*\*

\*\* Parameters unaffected were:

\*\* No. premature births

\*\* Female mortality

\*\* No. corpora lutea

\*\* No. implantation sites

\*\* Pre-implantation losses

\*\* Viable male fetuses

\*\* Viable female fetuses

\*\* No. dead fetuses

\*\*

\*\*

\*\* Fetal evaluations

\*\*

\*\* fetal body weights were significantly reduced in fetuses  
exposed in utero to HVGO at doses in excess of 125  
mg/kg/day.

\*\* Although there were differences between control and treated  
crown-rump lengths they were not statistically significant.

\*\* At the time of external examination, malformations were  
observed in one fetus in the 1000 mg/kg/day group. The  
fetus was edematous and pale in color. Both hindpaws were  
malformed; the digits were reduced in size with a  
subcutaneous hematoma located at the distal most aspect of  
each of the digits.

\*\* Malformations of the vertebral column were restricted to the  
500 mg/kg/day group.

\*\* Although a variety of skeletal malformations were observed  
in treated and control groups the degree of aberrant  
development in control fetuses was not as severe as in the  
HVGO-exposed groups.

\*\* Visceral malformations were restricted to two fetuses in the  
500 mg/kg/day group. One fetus had microphthalmia and the  
other fetus had a diaphragmatic hernia which displaced the  
heart from the left to right hand side.

F008 IUC31

F020 3779  
EOR  
F002 40  
F010 5.11  
F004 1  
F005 TS  
F006 Heavy vacuum gasoil CAS 64741-57-7  
F007 Heavy vacuum gasoil CAS 64741-57-7  
F008 IUC31  
F020 3780  
EOR  
F002 40  
F010 5.11  
F004 2  
F005 RM  
F006 Heavy vacuum gas oil is used as a starting material for base  
\*\* oil production. As such, it can be considered a "worst case"  
\*\* example of the unrefined/mildly refined base oil  
\*\* subcategory. Studies on this material are summarized below.  
F007 Heavy vacuum gas oil is used as a starting material for base  
\*\* oil production. As such, it can be considered a "worst case"  
\*\* example of the unrefined/mildly refined base oil  
\*\* subcategory. Studies on this material are summarized below.  
F008 IUC31  
F020 3781  
EOR  
F002 40  
F010 5.11  
F004 3  
F005 ME  
F006 Undiluted heavy vacuum gas oil was applied at doses of 0,  
\*\* 30, 125, 500 and 2000 mg/kg/day to the shorn skin of groups  
\*\* of ten male and ten female Sprague Dawley rats. The material  
\*\* was applied 5 days each week for 13 weeks. Collars were  
\*\* fitte  
F007 Undiluted heavy vacuum gas oil was applied at doses of 0,  
\*\* 30, 125, 500 and 2000 mg/kg/day to the shorn skin of groups  
\*\* of ten male and ten female Sprague Dawley rats. The material  
\*\* was applied 5 days each week for 13 weeks. Collars were  
\*\* fitted to the animals to prevent oral ingestion.  
\*\* Body weights were recorded weekly throughout the study and  
\*\* clinical observations were made daily. Skin irritation was  
\*\* assessed weekly. At 5 and 13 weeks blood samples were taken  
\*\* for hematological and clinical chemical analyses. At the end  
\*\* of the study (13 weeks) all surviving animals were  
\*\* sacrificed and a gross necropsy examination was performed.  
\*\* 20 tissues were preserved for subsequent histopathological  
\*\* examination.  
F008 IUC31  
F020 3782  
EOR  
F002 40  
F010 5.11  
F004 3  
F005 RE  
F006 Mobil (1988)  
\*\* Thirteen-week dermal administration of heavy vacuum gas oil

\*\* to rats.  
\*\* Study No. 61590  
\*\* Mobil Environmental and Health Science Laboratory  
F007 Mobil (1988)  
\*\* Thirteen-week dermal administration of heavy vacuum gas oil  
\*\* to rats.  
\*\* Study No. 61590  
\*\* Mobil Environmental and Health Science Laboratory  
F008 IUC31  
F020 3783  
EOR  
F002 40  
F010 5.11  
F004 3  
F005 RL  
F006 The report evaluated was incomplete but nevertheless was  
\*\* sufficient to identify the relevant effects of exposure to  
\*\* the test material.  
F007 The report evaluated was incomplete but nevertheless was  
\*\* sufficient to identify the relevant effects of exposure to  
\*\* the test material.  
F008 IUC31  
F020 3784  
EOR  
F002 40  
F010 5.11  
F004 3  
F005 RS  
F006 Two males and one female in the high dose group died during  
\*\* the study. The male deaths were considered to be compound  
\*\* related but the female death was considered incidental.  
\*\* Growth rates of males and females in the highest dose group  
\*\* were r  
F007 Two males and one female in the high dose group died during  
\*\* the study. The male deaths were considered to be compound  
\*\* related but the female death was considered incidental.  
\*\* Growth rates of males and females in the highest dose group  
\*\* were reduced compared to controls. At 13 weeks the males  
\*\* weighed 20% less and the females 15% less than controls.  
\*\* At 2000 mg/kg/day males and females had reduced erythrocytes  
\*\* and reduced platelets at 5 and 13 weeks. Similar effects  
\*\* were also found in the 500 mg/kg/day females.  
\*\*  
\*\* Clinical chemical changes in males and females at 2000  
\*\* mg/kg/day consisted of:  
\*\* twofold increase in sorbitol dehydrogenase  
\*\* twofold increase in cholesterol  
\*\* 50% reduction in uric acid  
\*\* In addition in females at 500 mg/kg/day, glucose was reduced  
\*\* and in the 500 mg/kg males cholesterol was increased.  
\*\*  
\*\* At gross necropsy, relative thymus weights were reduced in  
\*\* the 500 (by 25%) and 2000 mg/kg/day (by 50%) animals of both  
\*\* sexes. Relative liver weights were also increased at 500 and  
\*\* 2000 mg/kg/day for both sexes.  
\*\*  
\*\* Histological examination revealed decreased erythropoiesis

\*\* and fibrosis of the bone marrow in the 2000 mg/kg/day males.  
\*\* There was a reduction in thymic lymphocytes in the  
\*\* 2000 mg/kg/day groups (marked for males and moderate for  
\*\* females) and a slight reduction in the 500 mg/kg/day groups  
\*\* for both sexes.

\*\* No effects were found on either sperm morphology or in the  
\*\* results of the urinalysis.

\*\* The NOEL for both males and females was found to be 125  
\*\* mg/kg/day.

F008 IUC31

F020 3785

EOB

F002 40

F010 5.2.1

F004 1

F005 ME

F006 0.5 ml of undiluted test material was applied to the shorn  
\*\* dorsal skin in two areas on each of 6 male rabbits. One area  
\*\* was intact and the other abraded skin. The treated area was  
\*\* then covered with an occlusive dressing.

\*\* After 24 hours, the

F007 0.5 ml of undiluted test material was applied to the shorn  
\*\* dorsal skin in two areas on each of 6 male rabbits. One area  
\*\* was intact and the other abraded skin. The treated area was  
\*\* then covered with an occlusive dressing.

\*\* After 24 hours, the dressing was removed and the treated  
\*\* skin

\*\* was wiped to remove any residue of test material. The degree  
\*\* of erythema and edema was recorded according to the Draize  
\*\* scale. A second reading of skin responses was made at 72  
\*\* hours and again at 96 hours, 7 and 14 days. Results of the  
\*\* 24 and 72-hour readings were used to determine the Primary  
\*\* Irritation Index.

F008 IUC31

F020 3786

EOB

F002 40

F010 5.2.1

F004 1

F005 RE

F006 American Petroleum Institute (1986)

\*\* Acute oral toxicity study in rats

\*\* Acute dermal toxicity study in rabbits

\*\* Primary dermal irritation study in rabbits

\*\* Primary eye irritation study in rabbits

\*\* Dermal sensitization study in Guinea pigs

\*\* API 84

F007 American Petroleum Institute (1986)

\*\* Acute oral toxicity study in rats

\*\* Acute dermal toxicity study in rabbits

\*\* Primary dermal irritation study in rabbits

\*\* Primary eye irritation study in rabbits

\*\* Dermal sensitization study in Guinea pigs

\*\* API 84-01 Light paraffinic distillate CAS 64741-50-0

\*\* API Med. Res. Publ.: 33-30595

F008 IUC4  
F009 11-09-2010  
F020 3787

EOR

F002 40  
F010 5.2.1  
F004 1

F005 RS

F006 One animal died on day 10 even though there had been no  
\*\* signs of ill health previously. Irritation scores given  
\*\* below are averages from 5 animals.  
\*\*

Observation	Erythema	Edema	Average		Score
period	Intact	Abraded	Intact	Abraded	
24 h					

F007 One animal died on day 10 even though there had been no  
\*\* signs of ill health previously. Irritation scores given  
\*\* below are averages from 5 animals.  
\*\*

Observation	Erythema	Edema	Average		Score
period	Intact	Abraded	Intact	Abraded	
24 hrs.	2.3	2.5	2.3	4.8	
72 hrs.	1.8	2.0	2.0	3.8	
96 hrs.	1.5	1.7	1.0	2.6	
7 days	0.3	0.3	0.5	0.8	
14 days	0	0	0	0	

\*\* Primary dermal irritation index: 4.3

F008 IUC31  
F020 3788

EOR

F002 40  
F010 5.2.1  
F004 2  
F005 ME

F006 0.5 ml of undiluted test material was applied to the shorn  
\*\* skin in two areas on each of 6 male rabbits. One area was  
\*\* intact and the other abraded skin. The treated area was then  
\*\* covered with an occlusive dressing.

\*\* After 24 hours, the dressi

F007 0.5 ml of undiluted test material was applied to the shorn  
\*\* skin in two areas on each of 6 male rabbits. One area was  
\*\* intact and the other abraded skin. The treated area was then  
\*\* covered with an occlusive dressing.

\*\* After 24 hours, the dressing was removed and the treated  
\*\* skin

\*\* was wiped to remove any residue of test material. The degree  
\*\* of erythema and edema was recorded according to the Draize  
\*\* scale. A second reading of skin responses was made at 72  
\*\* hours and again at 96 hours, 7 and 14 days. Results of the  
\*\* 24 and 72-hour readings were used to determine the Primary  
\*\* Irritation Index.

F008 IUC31  
F020 3789

EOR

F002 40  
 F010 5.2.1  
 F004 2  
 F005 RE  
 F006 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in Guinea pigs  
 \*\* API 83  
 F007 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in Guinea pigs  
 \*\* API 83-12 Hydrotreated light naphthenic distillate CAS  
 \*\* 64742-53-6  
 \*\* API Med. Res. Publ.: 33-30592

F008 IUC4  
 F009 11-09-2010  
 F020 3790

EOR

F002 40  
 F010 5.2.1  
 F004 2  
 F005 RS

F006 Average Irritation scores are given below:

Observation period	Erythema		Edema		Average		Score
	Intact		Abraded		Intact	Abraded	
24 hrs.		2.3	2.3	2.7	2.7	5.0	
72 hrs.		3.0	3.0	2.5	3.0	5.8	
96 hrs.		2.7	2.8	2.7	3.0	5.6	
7 days	1.3	2.2	0				

F007 Average Irritation scores are given below:

Observation period	Erythema		Edema		Average		Score
	Intact		Abraded		Intact	Abraded	
24 hrs.		2.3	2.3	2.7	2.7	5.0	
72 hrs.		3.0	3.0	2.5	3.0	5.8	
96 hrs.		2.7	2.8	2.7	3.0	5.6	
7 days	1.3	2.2	0.8	1.7	3.0		
14 days		0	0	0	0	0	

\*\*  
 \*\* Primary dermal irritation index: 5.4

F008 IUC31  
 F020 3791  
 EOR  
 F002 40  
 F010 5.2.1  
 F004 3  
 F005 RE  
 F006 American Petroleum Institute (1982)

\*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F008 IUC31  
F020 3792  
EOR  
F002 40  
F010 5.2.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F008 IUC31  
F020 3793  
EOR  
F002 40  
F010 5.2.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F008 IUC31  
F020 3794  
EOR  
F002 40  
F010 5.2.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F008 IUC31  
F020 3795  
EOR  
F002 40  
F010 5.2.1

F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F008 IUC31  
F020 3796  
EOR  
F002 40  
F010 5.2.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066  
F008 IUC31  
F020 3797  
EOR  
F002 40  
F010 5.2.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33068  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33068  
F008 IUC31  
F020 3798  
EOR  
F002 40  
F010 5.2.1  
F004 3  
F005 RE  
F006 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in guinea pigs  
\*\* API sa  
F007 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits

\*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in guinea pigs  
 \*\* API sample 83-15 hydrotreated heavy naphthenic distillate  
 \*\* (CAS 64742-52-5)  
 \*\* API Health Environ. Sci. Dep. Rep. 33-32639  
 F008 IUC31  
 F020 3799  
 EOR  
 F002 40  
 F010 5.2.1  
 F004 3  
 F005 RE  
 F006 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F007 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F008 IUC31  
 F020 3800  
 EOR  
 F002 40  
 F010 5.2.1  
 F004 3  
 F005 RM  
 F006 CONCAWE summarized the data available on skin irritation for  
 \*\* the lubricating oil base stocks. The data are shown in the  
 \*\* following table.  
 \*\*  
 \*\*  
 \*\* Paraffinic distillates Irritation\* API Report  
 \*\*  
 \*\* Solvent dewaxed, light  
 \*\* API 78-9 (64  
 F007 CONCAWE summarized the data available on skin irritation for  
 \*\* the lubricating oil base stocks. The data are shown in the  
 \*\* following table.  
 \*\*  
 \*\*  
 \*\* Paraffinic distillates Irritation\* API Report  
 \*\*  
 \*\* Solvent dewaxed, light  
 \*\* API 78-9 (64742-56-9) Slight (0.6) 29-33104  
 \*\* Solvent dewaxed, heavy  
 \*\* API 78-10\*\*\* (64742-56-0) Non (0.27) 29-33105  
 \*\* API 79-3 (64742-65-0) Non (0.33) 29-33067  
 \*\* API 79-4 (64742-65-0) Non (0.34) 29-33066  
 \*\* API 79-5 (64742-65-0) Non (0.38) 29-33068  
 \*\*  
 \*\* White mineral oil\*\*\* Slight Hoekstra & Phillips  
 \*\*  
 \*\* Naphthenic distillates  
 \*\*  
 \*\* Solvent refined, light

\*\* API 78-5 (64741-97-5) Slight (0.65) 29-33106  
 \*\* Solvent refined, heavy  
 \*\* API 79-1 (64741-96-4) Slight (0.8) 29-33065  
 \*\* Hydrotreated, heavy  
 \*\* API 83-15 (64742-52-5) Slight (1.3)\*\* 33-32639  
 \*\*  
 \*\*  
 \*\* \* NB Irritation described as slight, moderate or  
 \*\* non-irritating in the original reports (Mean irritation score  
 given in  
 \* parentheses)  
 \*\*  
 \*\* \*\* Irritation index  
 \*\*  
 \*\* \*\*\* Although these materials are not included in the HPV Lubricating  
 \* base stocks category, they are similar to other materials in the  
 \* category and provide supportive information.  
 F008 IUC31  
 F020 3801  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 1  
 F005 ME  
 F006 0.1 ml of undiluted test material was applied to the corneal  
 \*\* surface of one eye of each of 9 rabbits, the other eye was  
 \*\* untreated and served as control.  
 \*\* After 20 to 30 seconds, the treated eyes of 3 rabbits were  
 \*\* washed with lukewarm water f  
 F007 0.1 ml of undiluted test material was applied to the corneal  
 \*\* surface of one eye of each of 9 rabbits, the other eye was  
 \*\* untreated and served as control.  
 \*\* After 20 to 30 seconds, the treated eyes of 3 rabbits were  
 \*\* washed with lukewarm water for 1 minute. Eyes of the other 6  
 \*\* rabbits were not washed.  
 \*\* Readings of ocular lesions for all animals were made at 1,  
 \*\* 24, 48, 72 hours and 7 days after treatment. Sodium  
 \*\* fluorescein was used to aid in revealing possible corneal  
 \*\* injury.  
 F008 IUC31  
 F020 3802  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 1  
 F005 RE  
 F006 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in Guinea pigs  
 \*\* API 84  
 F007 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits

\*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in Guinea pigs  
 \*\* API 84-01 Light paraffinic distillate CAS 64741-50-0  
 \*\* API Med. Res. Publ.: 33-30595  
 F008 IUC4  
 F009 11-09-2010  
 F020 3803  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 1  
 F005 RS  
 F006 One animal died on day 7 but this was not considered to be  
 \*\* treatment related.  
 \*\* The test material did not cause a pain response, corneal or  
 \*\* iridial irritation. The eye irritation that occurred had  
 \*\* cleared by 48 hours.  
 \*\* The primary eye irritati  
 F007 One animal died on day 7 but this was not considered to be  
 \*\* treatment related.  
 \*\* The test material did not cause a pain response, corneal or  
 \*\* iridial irritation. The eye irritation that occurred had  
 \*\* cleared by 48 hours.  
 \*\* The primary eye irritation scores (according to the standard  
 \*\* Draize scoring procedure) were as follows:  
 \*\*  

Period	Unwashed	Washed
eyes	eyes	
1 hour	3.0	4.0
24 hours	1.7	0

 \*\* Scores of 0 were recorded at all other observation times.  
 F008 IUC31  
 F020 3804  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 2  
 F005 ME  
 F006 0.1 ml of undiluted test material was applied to the corneal  
 \*\* surface of one eye of each of 9 rabbits, the other eye was  
 \*\* untreated and served as control.  
 \*\* After 20 to 30 seconds, the treated eyes of 3 rabbits were  
 \*\* washed with lukewarm water f  
 F007 0.1 ml of undiluted test material was applied to the corneal  
 \*\* surface of one eye of each of 9 rabbits, the other eye was  
 \*\* untreated and served as control.  
 \*\* After 20 to 30 seconds, the treated eyes of 3 rabbits were  
 \*\* washed with lukewarm water for 1 minute. Eyes of the other 6  
 \*\* rabbits were not washed.  
 \*\* Readings of ocular lesions for all animals were made at 1,  
 \*\* 24, 48, 72 hours and 7 days after treatment. Sodium  
 \*\* fluorescein was used to aid in revealing possible corneal  
 \*\* injury.  
 F008 IUC31  
 F020 3805  
 EOR

F002 40  
 F010 5.2.2  
 F004 2  
 F005 RE  
 F006 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in Guinea pigs  
 \*\* API 83  
 F007 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in Guinea pigs  
 \*\* API 83-12 Hydrotreated light naphthenic distillate CAS  
 \*\* 64742-53-6  
 \*\* API Med. Res. Publ.: 33-30592  
 F008 IUC4  
 F009 11-09-2010  
 F020 3806  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 2  
 F005 RS  
 F006 There was no pain response during instillation of the test  
 \*\* material and no corneal or iridial irritation was seen  
 \*\* during the study.  
 \*\* Any irritation that occurred had cleared by 48 hours.  
 \*\* The primary eye irritation scores for the first 48 hou  
 F007 There was no pain response during instillation of the test  
 \*\* material and no corneal or iridial irritation was seen  
 \*\* during the study.  
 \*\* Any irritation that occurred had cleared by 48 hours.  
 \*\* The primary eye irritation scores for the first 48 hours of  
 \*\* the study were as follows:  
 \*\* Period Unwashed Washed  
 \*\* eyes eyes  
 \*\* 1 hour 2.7 2.0  
 \*\* 24 hours 0.3 0  
 \*\* 48 hours 0 0  
 F008 IUC31  
 F020 3807  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 3  
 F005 RE  
 F006 American Petroleum Institute (1982)  
 \*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
 \*\* SUS/100 °F)  
 \*\* API Med. Res. Publ. 29-33105  
 F007 American Petroleum Institute (1982)  
 \*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150

\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F008 IUC31  
F020 3808  
EOR  
F002 40  
F010 5.2.2  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F008 IUC31  
F020 3809  
EOR  
F002 40  
F010 5.2.2  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F008 IUC31  
F020 3810  
EOR  
F002 40  
F010 5.2.2  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F008 IUC31  
F020 3811  
EOR  
F002 40  
F010 5.2.2  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)

\*\* API Med. Res. Publ. 29-33067  
 F007 American Petroleum Institute (1982)  
 \*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
 \*\* SUS/100 °F)  
 \*\* API Med. Res. Publ. 29-33067  
 F008 IUC31  
 F020 3812  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 3  
 F005 RE  
 F006 American Petroleum Institute (1982)  
 \*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
 \*\* SUS/100 °F)  
 \*\* API Med. Res. Publ. 29-33066  
 F007 American Petroleum Institute (1982)  
 \*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
 \*\* SUS/100 °F)  
 \*\* API Med. Res. Publ. 29-33066  
 F008 IUC31  
 F020 3813  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 3  
 F005 RE  
 F006 American Petroleum Institute (1982)  
 \*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
 \*\* SUS/100 °F)  
 \*\* API Med. Res. Publ. 29-33068  
 F007 American Petroleum Institute (1982)  
 \*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
 \*\* SUS/100 °F)  
 \*\* API Med. Res. Publ. 29-33068  
 F008 IUC31  
 F020 3814  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 3  
 F005 RE  
 F006 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in guinea pigs  
 \*\* API sa  
 F007 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in guinea pigs  
 \*\* API sample 83-15 hydrotreated heavy naphthenic distillate  
 \*\* (CAS 64742-52-5)

\*\* API Health Environ. Sci. Dep. Rep. 33-32639  
 F008 IUC31  
 F020 3815  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 3  
 F005 RE  
 F006 Carpenter, C. P. and Smythe, H. F. (1946)  
 \*\* Chemical burns of the rabbit cornea  
 \*\* Am. J. Ophthal. Vol. 29, pp 1363-1372  
 F007 Carpenter, C. P. and Smythe, H. F. (1946)  
 \*\* Chemical burns of the rabbit cornea  
 \*\* Am. J. Ophthal. Vol. 29, pp 1363-1372  
 F008 IUC31  
 F020 3816  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 3  
 F005 RE  
 F006 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F007 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F008 IUC31  
 F020 3817  
 EOR  
 F002 40  
 F010 5.2.2  
 F004 3  
 F005 RM  
 F006 CONCAWE summarized the data available on eye irritation for  
 \*\* the lubricating oil base stocks. The data are shown in the  
 \*\* following table.  
 \*\*  
 \*\* Paraffinic distillates Irritation\* API report No.  
 \*\* Solvent dewaxed, light  
 \*\* API 78-9 (64742-56-9) S  
 F007 CONCAWE summarized the data available on eye irritation for  
 \*\* the lubricating oil base stocks. The data are shown in the  
 \*\* following table.  
 \*\*  
 \*\* Paraffinic distillates Irritation\* API report No.  
 \*\* Solvent dewaxed, light  
 \*\* API 78-9 (64742-56-9) Slight 29-33104  
 \*\* Solvent dewaxed, heavy  
 \*\* API 78-10\*\* (64742-56-0) Non 29-33105  
 \*\* API 79-3 (64742-65-0) Non 29-33067  
 \*\* API 79-4 (64742-65-0) Non 29-33066  
 \*\* API 79-5 (64742-65-0) Non 29-33068  
 \*\*  
 \*\* Naphthenic distillates

\*\*  
 \*\* Solvent refined, light  
 \*\* API 78-5 (64741-97-5) Non 29-33106  
 \*\* Solvent refined, heavy  
 \*\* API 79-1 (64741-96-4) Non 29-33065  
 \*\* Hydrotreated, heavy  
 \*\* API 83-15 (64742-52-5) Slight 33-32639  
 \*\*  
 \*\* Other mineral oils  
 \*\*  
 \*\* Paraffin oil\*\* Slight Carpenter & Smyth  
 \*\*  
 \*\* \* Irritation described as slight, moderate or  
 \*\* non-irritating  
 \*\*  
 \*\* \*\* Although these materials are not included in the HPV Lubricating  
 base  
 \* stocks category, they are similar to other materials in the category  
 \* and provide supportive information.  
 F008 IUC31  
 F020 3818  
 EOR  
 F002 40  
 F010 5.3  
 F004 1  
 F005 ME  
 F006 0.4 ml of a 25% mixture of test material and paraffin oil  
 \*\* was applied under an occlusive dressing to the shorn skin of  
 \*\* 10 male and 10 female animals. 6 hours after application the  
 \*\* dressings were removed and the skin wiped to remove residue  
 F007 0.4 ml of a 25% mixture of test material and paraffin oil  
 \*\* was applied under an occlusive dressing to the shorn skin of  
 \*\* 10 male and 10 female animals. 6 hours after application the  
 \*\* dressings were removed and the skin wiped to remove residues  
 \*\* of test material. The animals received one application each  
 \*\* week for 3 weeks. The same application site was used each  
 \*\* time. 2 weeks following the third application, a challenge  
 \*\* dose (0.4 ml of a 1% mixture in paraffin oil) was applied  
 \*\* in the same manner as the sensitizing doses. A previously  
 \*\* untreated site was used for the challenge application.  
 \*\* The application sites for sensitizing and challenge doses  
 \*\* were read for erythema and edema 24 and 48 hours after patch  
 \*\* removal. To assist in the reading of the response to the  
 \*\* final challenge dose the test site was depilated 3 hours  
 \*\* prior to reading by using a commercially available  
 \*\* depilatory cream.  
 \*\*  
 \*\* Positive control (2,4-dinitrochlorobenzene at 0.3% in 80%  
 \*\* aqueous ethanol), vehicle control and naive control groups  
 \*\* were included in this study and the procedure for these was  
 \*\* the same as for the test groups.  
 F008 IUC31  
 F020 3819  
 EOR  
 F002 40  
 F010 5.3  
 F004 1

F005 RE  
F006 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 84  
F007 American Petroleum Institute (1986)  
\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 84-01 Light paraffinic distillate CAS 64741-50-0  
\*\* API Med. Res. Publ.: 33-30595  
F008 IUC4  
F009 11-09-2010  
F020 3820  
EOR  
F002 40  
F010 5.3  
F004 1  
F005 RS  
F006 The criteria used to evaluate the responses are described in  
\*\* the report as follows:  
\*\* Determination of sensitization was based upon reactions to  
\*\* the challenge dose. Grades of 1 or greater in the test  
\*\* animals indicate evidence of sensitization  
F007 The criteria used to evaluate the responses are described in  
\*\* the report as follows:  
\*\* Determination of sensitization was based upon reactions to  
\*\* the challenge dose. Grades of 1 or greater in the test  
\*\* animals indicate evidence of sensitization, provided grades  
\*\* of less than 1 are seen in the naive controls. If grades of  
\*\* 1 or greater are noted in the naive control animals, then  
\*\* the reactions of test animals that exceed the most severe  
\*\* naive control reaction are considered sensitization  
\*\* reactions.  
\*\*  
\*\* Using these criteria, none of the test animals became  
\*\* sensitized following treatment with API 84-01. In contrast,  
\*\* all the positive control animals were sensitized by their  
\*\* treatment.  
F008 IUC31  
F020 3821  
EOR  
F002 40  
F010 5.3  
F004 2  
F005 ME  
F006 0.4 ml of a 50% mixture of test material and paraffin oil  
\*\* was applied under an occlusive dressing to the shorn skin of  
\*\* 10 male and 10 female animals. 6 hours after application,  
\*\* the  
\*\* dressings were removed and the skin wiped to remove residu  
F007 0.4 ml of a 50% mixture of test material and paraffin oil

\*\* was applied under an occlusive dressing to the shorn skin of  
\*\* 10 male and 10 female animals. 6 hours after application,  
\*\* the  
\*\* dressings were removed and the skin wiped to remove residues  
\*\* of test material. The animals received one application each  
\*\* week for 3 weeks. The same application site was used each  
\*\* time. 2 weeks following the third application, a challenge  
\*\* dose (0.4 ml of a 1% mixture in paraffin oil) was applied  
\*\* in the same manner as the sensitizing doses. A previously  
\*\* untreated site was used for the challenge application.  
\*\* The application sites for sensitizing and challenge doses  
\*\* were read for erythema and edema 24 and 48 hours after patch  
\*\* removal. To assist in the reading of the response to the  
\*\* final challenge dose the test site was depilated 3 hours  
\*\* prior to reading by using a commercially available  
\*\* depilatory cream.  
\*\*

\*\* Positive control (2,4-dinitrochlorobenzene at 0.3% in 80%  
\*\* aqueous ethanol), vehicle control and naive control groups  
\*\* were included in this study and the procedure for these was  
\*\* the same as for the test groups.

F008 IUC31

F020 3822

EOR

F002 40

F010 5.3

F004 2

F005 RE

F006 American Petroleum Institute (1986)

\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 83

F007 American Petroleum Institute (1986)

\*\* Acute oral toxicity study in rats  
\*\* Acute dermal toxicity study in rabbits  
\*\* Primary dermal irritation study in rabbits  
\*\* Primary eye irritation study in rabbits  
\*\* Dermal sensitization study in Guinea pigs  
\*\* API 83-12 Hydrotreated light naphthenic distillate CAS  
\*\* 64742-53-6  
\*\* API Med. Res. Publ.: 33-30592

F008 IUC4

F009 11-09-2010

F020 3823

EOR

F002 40

F010 5.3

F004 2

F005 RS

F006 The criteria used to evaluate the responses are described in  
\*\* the report as follows:

\*\* Determination of sensitization was based upon reactions to  
\*\* the challenge dose. Grades of 1 or greater in the test  
\*\* animals indicate evidence of sensitization

F007 The criteria used to evaluate the responses are described in  
\*\* the report as follows:  
\*\* Determination of sensitization was based upon reactions to  
\*\* the challenge dose. Grades of 1 or greater in the test  
\*\* animals indicate evidence of sensitization, provided grades  
\*\* of less than 1 are seen in the naive controls. If grades of  
\*\* 1 or greater are noted in the naive control animals, then  
\*\* the reactions of test animals that exceed the most severe  
\*\* naive control reaction are considered sensitization  
\*\* reactions.  
\*\*  
\*\* One animal had a score of 0.5 after challenge with API  
\*\* 83-12. In contrast, all the positive control animals were  
\*\* sensitized by their treatment. The sample of API 83-12 was  
\*\* therefore non sensitizing.

F008 IUC31  
F020 3824  
EOR  
F002 40  
F010 5.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F008 IUC31  
F020 3825  
EOR  
F002 40  
F010 5.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F008 IUC31  
F020 3826  
EOR  
F002 40  
F010 5.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F007 American Petroleum Institute (1982)

\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F008 IUC31  
F020 3827  
EOR  
F002 40  
F010 5.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F008 IUC31  
F020 3828  
EOR  
F002 40  
F010 5.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F008 IUC31  
F020 3829  
EOR  
F002 40  
F010 5.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066  
F008 IUC31  
F020 3830  
EOR  
F002 40  
F010 5.3  
F004 3  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800

\*\* SUS/100 °F)  
 \*\* API Med. Res. Publ. 29-33068  
 F007 American Petroleum Institute (1982)  
 \*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
 \*\* SUS/100 °F)  
 \*\* API Med. Res. Publ. 29-33068  
 F008 IUC31  
 F020 3831  
 EOR  
 F002 40  
 F010 5.3  
 F004 3  
 F005 RE  
 F006 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in guinea pigs  
 \*\* API sa  
 F007 American Petroleum Institute (1986)  
 \*\* Acute oral toxicity study in rats  
 \*\* Acute dermal toxicity study in rabbits  
 \*\* Primary dermal irritation study in rabbits  
 \*\* Primary eye irritation study in rabbits  
 \*\* Dermal sensitization study in guinea pigs  
 \*\* API sample 83-15 hydrotreated heavy naphthenic distillate  
 \*\* (CAS 64742-52-5)  
 \*\* API Health Environ. Sci. Dep. Rep. 33-32639  
 F008 IUC31  
 F020 3832  
 EOR  
 F002 40  
 F010 5.3  
 F004 3  
 F005 RE  
 F006 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F007 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F008 IUC31  
 F020 3833  
 EOR  
 F002 40  
 F010 5.3  
 F004 3  
 F005 RM  
 F006 CONCAWE summarized the data available on skin sensitization  
 \*\* for the lubricating oil basestocks. The methods and  
 \*\* criteria used were the same as those described in the  
 \*\* previous two robust summaries. The data are shown in the  
 \*\* following table.  
 F007 CONCAWE summarized the data available on skin sensitization

\*\* for the lubricating oil basestocks. The methods and  
 \*\* criteria used were the same as those described in the  
 \*\* previous two robust summaries. The data are shown in the  
 \*\* following table.

** Paraffinic distillates	Sensitization	API Report
** Solvent dewaxed, light		
** API 78-9 64742-56-9 Non	29-33104	
** Solvent dewaxed, heavy		
** API 78-10* 64742-56-0 Non	29-33105	
** API 79-3 64742-65-0 Non	29-33067	
** API 79-4 64742-65-0 Non	29-33066	
** API 79-5 64742-65-0 Non	29-33068	

** Naphthenic distillates		
** Solvent refined, light		
** API 78-5 64741-97-5 Non	29-33106	
** Solvent refined, heavy		
** API 79-1 64741-96-4 Non	29-33065	
** Hydrotreated, heavy		
** API 83-15 64742-52-5 Non	33-32639	

\*\* \* Although this material is not included in the HPV Lubricating  
 base stocks category, it is similar to other materials in the category and  
 \* provides supportive information.

F008 IUC31

F020 3834

EOR

F002 40

F010 5.4

F004 2

F005 ME

F006 Undiluted API 83-12 was applied at doses of 200, 1000 and  
 \*\* 2000 mg/kg/day to the shorn dorsal skin of groups of five  
 \*\* male and five female rabbits. The test material was applied  
 \*\* to the skin 3 times each week for 4 weeks (12 applications  
 \*\* total

F007 Undiluted API 83-12 was applied at doses of 200, 1000 and  
 \*\* 2000 mg/kg/day to the shorn dorsal skin of groups of five  
 \*\* male and five female rabbits. The test material was applied  
 \*\* to the skin 3 times each week for 4 weeks (12 applications  
 \*\* total). The applied material was covered with an occlusive  
 \*\* dressing for 6 hours, which was then removed and the skin  
 \*\* was  
 \*\* wiped with a dry gauze to remove any residual material. A  
 \*\* group of five rabbits of each sex served as sham controls.  
 \*\* The test skin site of each animal was examined and scored  
 \*\* for irritation prior to each application of test material.  
 \*\* Mortality and moribundity checks were performed twice daily  
 \*\* and body weights were recorded weekly.  
 \*\* At termination, blood samples were taken for a range of  
 \*\* hematological and clinical chemical measurements. Urine  
 \*\* samples were also collected and frozen for possible future  
 \*\* examination.

\*\* A complete gross necropsy was performed on all animals.

\*\* Major organs were weighed and tissues were processed for  
 \*\* subsequent histopathological examination.  
 F008 IUC31  
 F020 3835  
 EOR  
 F002 40  
 F010 5.4  
 F004 2  
 F005 RE  
 F006 American Petroleum Institute (1986)  
 \*\* 28 day dermal toxicity study in the rabbit  
 \*\* API 83-12 Hydrotreated light naphthenic distillate CAS  
 \*\* 64742-53-6  
 \*\*  
 \*\* API Med. Res. Publ. 33-30499  
 F007 American Petroleum Institute (1986)  
 \*\* 28 day dermal toxicity study in the rabbit  
 \*\* API 83-12 Hydrotreated light naphthenic distillate CAS  
 \*\* 64742-53-6  
 \*\*  
 \*\* API Med. Res. Publ. 33-30499  
 F008 IUC4  
 F009 11-09-2010  
 F020 3836  
 EOR  
 F002 40  
 F010 5.4  
 F004 2  
 F005 RS  
 F006 No deaths occurred during the study.  
 \*\* Skin irritation occurred to varying degrees in all animals  
 \*\* treated with API 83-12. There was moderate irritation in  
 \*\* the high dose males and females. In the mid dose  
 \*\* group moderate irritation occurred in  
 F007 No deaths occurred during the study.  
 \*\* Skin irritation occurred to varying degrees in all animals  
 \*\* treated with API 83-12. There was moderate irritation in  
 \*\* the high dose males and females. In the mid dose  
 \*\* group moderate irritation occurred in the females and slight  
 \*\* irritation in the males. In the low dose group minimal  
 \*\* irritation occurred in both sexes. The overall mean  
 \*\* irritation scores were:  
 \*\*  

Dose level (mg/kg)	Males	Females
Control 0	0	0
200	0.1	0.4
1000	2.0	2.2
2000	2.6	3.1

 \*\*  
 \*\* Soft stool was also observed in several animals but this  
 \*\* also occurred in a control male was not considered to be  
 \*\* dose related. All high dose females appeared thin and this  
 \*\* was considered to be treatment related.  
 \*\* Body weight gains were reduced in the high dose males and  
 \*\* females and in the mid dose females when compared to  
 \*\* their respective controls.

\*\* Overall weight changes (kg) are shown in the following table

\*\*

\*\* Dose level      Males Females  
\*\* (mg/kg)

\*\* Control 0      +0.5    +0.3

\*\* 200            +0.3    +0.4

\*\* 1000           +0.3    0.0\*

\*\* 2000           +0.1\* -0.2\*

\*\*

\*\* \* statistically significant (p <= 0.05)

\*\*

\*\* Clinical chemical and hematological values were considered  
\*\* to be unaffected by treatment. A low value (cf control) for  
\*\* white cell count in the low dose female group was considered  
\*\* incidental since the value was within a normal range and was  
\*\* not a dose-related effect.

\*\*

\*\* Although there were some organ weight differences, they were  
\*\* considered incidental to treatment. The exception was for  
\*\* the absolute testis weights, which were lower in the high  
\*\* dose males and the relative weights of the right testis  
\*\* which were also lower than controls.

\*\*

\*\* At gross necropsy, findings for the skin consisted of dry,  
\*\* scaly, rough, fissured, crusted and/or thickened skin. This  
\*\* was a common finding in all treatment groups.

\*\*

\*\* Histopathological examination revealed slight to moderate  
\*\* proliferative changes in the skin in all rabbits in the  
\*\* high dose group. These changes were accompanied by an  
\*\* increased granulopoeisis of the bone marrow. The testes of  
\*\* 3 of the 5 males in the high dose group had bilateral  
\*\* diffuse tubular hypoplasia accompanied by aspermatogenesis  
\*\* and atrophy of the accessory sex organs. There were no  
\*\* changes observed in either the testes or epididymes of the  
\*\* male rabbits in the mid or low dose groups.  
\*\* No other treatment-related histopathological changes were  
\*\* recorded.

F008 IUC31

F020 3837

EOR

F002 40

F010 5.4

F004 3

F005 ME

F006 Three related, but separate studies were carried out at the  
\*\* same time on 6 different food grade white oils and 3 food  
\*\* grade waxes.

\*\* Only the information on the oils is included here. The  
\*\* information on waxes is included in the Waxes and Rela

F007 Three related, but separate studies were carried out at the  
\*\* same time on 6 different food grade white oils and 3 food  
\*\* grade waxes.

\*\* Only the information on the oils is included here. The  
\*\* information on waxes is included in the Waxes and Related  
\*\* Materials HPV Test Plan.

\*\*

\*\* In the main study, groups of 20 male and 20 female rats were  
\*\* fed diets containing one of 6 different white oils at  
\*\* dietary  
\*\* concentrations of 0.002, 0.02, 0.2 and 2.0% for 90 days.  
\*\* Further groups of 60 male and 60 females were fed untreated  
\*\* control diet. Additionally groups of 20 rats of each sex  
\*\* were fed diets containing 2.0% coconut oil.  
\*\*

\*\* The second study was a reversibility study. Groups of 10  
\*\* rats of each sex were fed diets for 90 days containing one  
\*\* of the 6 different oils at the 2.0% level or coconut oil at  
\*\* 2%. These animals were then fed control diet for 28 days  
\*\* following the 90-days treatment. Groups of 30 rats of each  
\*\* sex served as controls for this reversibility study.  
\*\*

\*\* A third study was designed to determine tissue levels of  
\*\* hydrocarbons. In this study, 5 rats of each sex were fed  
\*\* diets  
\*\* containing one of the 6 oils or coconut oil at the 2.0%  
\*\* dietary level for 90 days. Extra groups of rats (5 of each  
\*\* sex) were fed control diet or coconut oil or one of the  
\*\* six oils for 90 days followed by exposure to control diet  
\*\* only for a further 28 days.  
\*\*

\*\* In all three studies, animals were monitored for weight,  
\*\* food intakes and clinical condition throughout. An  
\*\* ophthalmic examination was performed prior to treatment and  
\*\* prior to necropsy on the animals in the main study and those  
\*\* for the study of reversibility.

\*\* A full necropsy was performed on the main and reversibility  
\*\* study animals and a full range of hematological parameters  
\*\* were measured on blood samples taken from the animals.  
\*\* Clinical chemical measurements were also made on serum  
\*\* separated from the blood samples. A selection of organs was  
\*\* weighed and a range of tissues retained for subsequent  
\*\* histopathological examination. All tissues from the high  
\*\* dose group and control groups were examined by light  
\*\* microscopy. Additionally the liver, lymph nodes, spleen,  
\*\* kidney, small intestine and lung were examined from all the  
\*\* intermediate dose groups.  
\*\* Mineral hydrocarbon levels were measured in a limited number  
\*\* of tissues in those animals designated for tissue level  
\*\* determinations.

F008 IUC31

F020 3838

EOR

F002 40

F010 5.4

F004 3

F005 RE

F006 BIBRA (1992)

\*\* A 90-day feeding study in the rat with six different mineral  
\*\* oils (N15(H), N70(H), N70(A), P15(H), N10(A) and P100(H),  
\*\* three different mineral waxes (a low melting point wax, a  
\*\* high melting point wax and a high sulphur wax) and

F007 BIBRA (1992)

\*\* A 90-day feeding study in the rat with six different mineral

\*\* oils (N15(H), N70(H), N70(A), P15(H), N10(A) and P100(H),  
 \*\* three different mineral waxes (a low melting point wax, a  
 \*\* high melting point wax and a high sulphur wax) and coconut  
 \*\* oil.  
 \*\* BIBRA project No. 3.1010  
 F008 IUC31  
 F020 3839  
 EOR  
 F002 40  
 F010 5.4  
 F004 3  
 F005 RE  
 F006 Firriolo, J. M., Morris, C. F., Trimmer, G. W., Twitty, L.  
 \*\* D., Smith, J. H. and Freeman, J. J. (1995)  
 \*\* Comparative 90-day feeding study with low-viscosity white  
 \*\* mineral oil in Fischer-344 and Sprague-Dawley-derived CRL:CD  
 \*\* rats.  
 \*\* Toxicologic P  
 F007 Firriolo, J. M., Morris, C. F., Trimmer, G. W., Twitty, L.  
 \*\* D., Smith, J. H. and Freeman, J. J. (1995)  
 \*\* Comparative 90-day feeding study with low-viscosity white  
 \*\* mineral oil in Fischer-344 and Sprague-Dawley-derived CRL:CD  
 \*\* rats.  
 \*\* Toxicologic Pathology Vol 23, No. 1, pages 26-33  
 F008 IUC4  
 F009 11-09-2010  
 F020 3840  
 EOR  
 F002 40  
 F010 5.4  
 F004 3  
 F005 RE  
 F006 McKee, R. H., Plutnick, R. T. and Traul, K. A. (1987)  
 \*\* Assessment of the potential reproductive and subchronic  
 \*\* toxicity of EDS coal liquids in Sprague-Dawley rats.  
 \*\* Toxicology Vol 46, pp 267-280  
 F007 McKee, R. H., Plutnick, R. T. and Traul, K. A. (1987)  
 \*\* Assessment of the potential reproductive and subchronic  
 \*\* toxicity of EDS coal liquids in Sprague-Dawley rats.  
 \*\* Toxicology Vol 46, pp 267-280  
 F008 IUC31  
 F009 23-09-2001  
 F020 3841  
 EOR  
 F002 40  
 F010 5.4  
 F004 3  
 F005 RM  
 F006 While only one report (three studies) is described here,  
 \*\* numerous repeat dose studies on white oils destined for use  
 \*\* in foods have been conducted and reported in the open  
 \*\* literature.  
 \*\*  
 \*\* Recent studies with a low molecular weight white oil h  
 F007 While only one report (three studies) is described here,  
 \*\* numerous repeat dose studies on white oils destined for use  
 \*\* in foods have been conducted and reported in the open

\*\* literature.  
 \*\*  
 \*\* Recent studies with a low molecular weight white oil have  
 \*\* demonstrated that the F 344 rat is more sensitive in its  
 \*\* response to mineral hydrocarbons than the Sprague Dawley rat  
 \*\* (Firriolo et al). Indeed other studies on white oils with  
 \*\* Sprague Dawley rats (McKee et al) and beagle dogs (Bird et  
 \*\* al) have also not resulted in any reported effects .  
 F008 IUC31  
 F020 3842  
 EOR  
 F002 40  
 F010 5.4  
 F004 3  
 F005 RS  
 F006 The six oils tested had average molecular weights ranging  
 \*\* from 320 to 510. The effects observed in the study were  
 \*\* inversely related to the oil's molecular weight. Thus the  
 \*\* oil with the lowest molecular weight caused the most severe  
 \*\* effects  
 F007 The six oils tested had average molecular weights ranging  
 \*\* from 320 to 510. The effects observed in the study were  
 \*\* inversely related to the oil's molecular weight. Thus the  
 \*\* oil with the lowest molecular weight caused the most severe  
 \*\* effects and at lower dose levels than the higher molecular  
 \*\* weight materials. For simplicity, only the results of the  
 \*\* highest and lowest molecular weight oils are summarized  
 \*\* below. Furthermore, the results of the reversibility study  
 \*\* are not given in detail here.  
 \*\* In general, there was evidence of reversibility of the  
 \*\* effects but reversibility was not complete for all of the  
 \*\* parameters measured.  
 \*\*  
 \*\* P 100 H (Average molecular weight 510)  
 \*\*  
 \*\* There were no treatment-related clinical signs, nor was  
 \*\* there an effect on body weight. Food consumption was  
 \*\* increased in the males of the highest dose group but this  
 \*\* was less than 10% greater than for the controls. Ophthalmic  
 \*\* examination did not reveal any effects. Organ weights,  
 \*\* hematology and clinical chemistry were unaffected except for  
 \*\* a 10% increase in ASAT in the males in the highest dose  
 \*\* group.  
 \*\* There were no treatment-related findings at necropsy and the  
 \*\* histological examination did not reveal any  
 \*\* treatment-related effects.  
 \*\* A small amount of mineral hydrocarbon was found in the  
 \*\* livers of the male rats in the highest dose group.  
 \*\*  
 \*\*  
 \*\* N 10 A (Average molecular weight 320)  
 \*\*  
 \*\* There were no treatment-related clinical signs, nor was  
 \*\* there an effect on body weight. Food consumption was  
 \*\* increased in the males of the highest dose group but this  
 \*\* was less than 10% greater than for the controls. Ophthalmic  
 \*\* examination did not reveal any effects.

\*\*

## \*\* Organ weights

\*\*

\*\* Increases in organ weights are as shown below, other organ  
\*\* weights were unaffected.

\*\*

\*\*                   Increases (%) at  
\*\* Organ               Dietary concentration

\*\*

	Males		Females		
	0.2%	2.0%	0.2%	2.0%	
Kidney (abs.)			4	6	5
(rel.)			7	7	
Liver (abs)	8	11	6	21	
(rel.)	6	12	8	23	
Spleen (abs.)					17
(rel.)		5		19	
MLN* (abs.)			224		220
(rel.)		224		226	

\*\*

\*\* \* NB Mesenteric Lymph Node weights only determined for  
\*\* the 2% dose group in the reversal group of animals and not  
\*\* for the main study animals.

\*\*

## \*\* Hematology

\*\*

\*\* In the males in the highest dose group there were increases  
\*\* in Neutrophils (41%), monocytes (28%) and basophils (200%)  
\*\* In the females, changes occurred in the 2% and 0.2% dose  
\*\* groups. These were as follows:

\*\*

	Change (% + or -)	
	0.2%	2%
RBC	- 2	- 3
Hemoglobin	- 2	- 3
WBC		+ 23
Differential WBC		
Neutrophils		+ 75
Monocytes		+ 51
Eosinophils		+ 38

\*\*

## \*\* Clinical chemistry

\*\*

\*\* In the males there was a reduction in Alkaline phosphatase  
\*\* of  
\*\* 8 and 2% in the 2 and 0.2% dose groups respectively.  
\*\* Changes in clinical chemical parameters in the females were  
\*\* as follows:

\*\*

	Change (% + or -)	
	0.2%	2%
ALKP	- 12	- 13
ASAT		+ 12
Gamma GT		+ 91

\*\* A/G ratio - 8

\*\* Histopathology

\*\* Liver

\*\* Liver lesions comprised microgranuloma or granuloma, the distinction between being purely related to size. Lesions were classified as microgranuloma if the average diameter was less than 25% of the average hepatic lobule. The histological features of the two were similar and consisted of collections of macrophages, some with necrotic cells surrounded by inflammatory cells and variable fibrosis.

\*\* No lesions were observed in the males whereas granulomas were seen in the females in the highest dose group. In females in the recovery group 28 days after cessation of exposure, the incidence was unchanged but the severity of the lesions had decreased.

\*\* Mesenteric Lymph node

\*\* The lymph node lesions comprised focal collections of macrophages, often in the cortical region. The macrophages were lightly vacuolated, giving a slightly foamy appearance to their cytoplasm. Some macrophages had a yellowish-brown pigmentation of varied intensity. The focal collections of macrophages were classified as histiocytosis and were scored as minimal, mild, moderate or marked based on size and abundance. The foci of histiocytosis were not homogeneously distributed; they were often restricted to one node or even to part of one node.

\*\* Histiocytosis was also found in control rats but was generally restricted to isolated foci and was always classified as minimal.

\*\* Compared to controls, in males histiocytosis increased down to the 0.2% dose group. In the females, histiocytosis was also observed in the 0.02% dose group.

\*\* In the reversibility group the severity and incidence was reduced after being fed control diet for 28 days.

\*\* Ileum and jejunum

\*\* There was a significant increase in vacuolation of the lamina propria in the high dose female group.

\*\* In summary, the NOELs and LOELs for the six oils that were tested are as follows.

Oil	LOEL	NOAEL
	(histiocytosis)	
	Dietary concentration	
N10A	0.02%	
N15H	0.002%	
P15H	0.02%	
N70A	0.02%	

```

**      N70H          0.02%
**      P100H         -          2.0%
F008 IUC31
F020 3843
EOR
F002 40
F010 5.4
F004 3
F005 TS
F006 Six white oils examined in this study were characterized.
**      Only the average molecular weight and viscosity at 100 °C
**      are shown below:
**
**      Sample          Viscosity      Average
**                  (cSt)          Molecular
**                  Weight
**
**      N10 (A)          3.08          320
**      N15 (H)          3.45          330
**      P15 (H)          3.5
F007 Six white oils examined in this study were characterized.
**      Only the average molecular weight and viscosity at 100 °C
**      are shown below:
**
**      Sample          Viscosity      Average
**                  (cSt)          Molecular
**                  Weight
**
**      N10 (A)          3.08          320
**      N15 (H)          3.45          330
**      P15 (H)          3.52          350
**      N70 (A)          7.88          410
**      N70 (H)          7.65          420
**      P100 (H)         11           510
F008 IUC31
F020 3844
EOR
F002 40
F010 5.4
F004 4
F005 AD
F006 Summary of dermal repeat dose studies.doc
F007 Summary of dermal repeat dose studies.doc
F020 3856
F021 Summary of dermal repeat dose studies
F022 39936
F023 13:2:2003 17:40
F024 doc
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 American Petroleum Institute (1982)
**      Acute toxicity tests of API sample 78-10 paraffinic oil (150
**      SUS/100 °F)
**      API Med. Res. Publ. 29-33105

```

F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-10 paraffinic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33105  
F008 IUC31  
F020 3845  
EOR  
F002 40  
F010 5.4  
F004 4  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-5 naphthenic oil (150  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33106  
F008 IUC31  
F020 3846  
EOR  
F002 40  
F010 5.4  
F004 4  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 78-9 paraffinic oil (70  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33104  
F008 IUC31  
F020 3847  
EOR  
F002 40  
F010 5.4  
F004 4  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-1 naphthenic oil (90  
\*\* SUS/210 °F)  
\*\* API Med. Res. Publ. 29-33065  
F008 IUC31  
F020 3848  
EOR  
F002 40  
F010 5.4  
F004 4  
F005 RE  
F006 American Petroleum Institute (1982)

\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-3 paraffinic oil (350  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33067  
F008 IUC31  
F020 3849  
EOR  
F002 40  
F010 5.4  
F004 4  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-4 paraffinic oil (550  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33066  
F008 IUC31  
F020 3850  
EOR  
F002 40  
F010 5.4  
F004 4  
F005 RE  
F006 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33068  
F007 American Petroleum Institute (1982)  
\*\* Acute toxicity tests of API sample 79-5 paraffinic oil (800  
\*\* SUS/100 °F)  
\*\* API Med. Res. Publ. 29-33068  
F008 IUC31  
F020 3851  
EOR  
F002 40  
F010 5.4  
F004 4  
F005 RE  
F006 American Petroleum Institute (1987)  
\*\* 28-Day dermal toxicity study in the rabbit.  
\*\* API sample 83-15 hydrotreated heavy naphthenic distillate  
\*\* (CAS 64742-52-5)  
\*\* API Helath Environ. Sci. Dep. Rep. 35-32430  
F007 American Petroleum Institute (1987)  
\*\* 28-Day dermal toxicity study in the rabbit.  
\*\* API sample 83-15 hydrotreated heavy naphthenic distillate  
\*\* (CAS 64742-52-5)  
\*\* API Helath Environ. Sci. Dep. Rep. 35-32430  
F008 IUC31  
F020 3852  
EOR

F002 40  
F010 5.4  
F004 4  
F005 RE  
F006 CONCAWE (1997)  
\*\* Lubricating oil basestocks  
\*\* Product dossier No. 97/108  
\*\* CONCAWE, Brussels  
F007 CONCAWE (1997)  
\*\* Lubricating oil basestocks  
\*\* Product dossier No. 97/108  
\*\* CONCAWE, Brussels  
F008 IUC31  
F020 3853  
EOR  
F002 40  
F010 5.4  
F004 4  
F005 RE  
F006 Trimmer, G. W. et al (1989)  
\*\* Evaluation of the dermal toxicity of paraffinic lube oils  
\*\* Toxicologist Vol 9, pp 162  
F007 Trimmer, G. W. et al (1989)  
\*\* Evaluation of the dermal toxicity of paraffinic lube oils  
\*\* Toxicologist Vol 9, pp 162  
F008 IUC31  
F020 3854  
EOR  
F002 40  
F010 5.4  
F004 4  
F005 RM  
F006 Data on repeated dose dermal studies in rabbits have been  
\*\* summarized elsewhere (CONCAWE 1997).  
\*\* The attached tabulated summary of information is taken from  
\*\* the CONCAWE publication.  
F007 Data on repeated dose dermal studies in rabbits have been  
\*\* summarized elsewhere (CONCAWE 1997).  
\*\* The attached tabulated summary of information is taken from  
\*\* the CONCAWE publication.  
F008 IUC31  
F020 3855  
EOR  
F002 40  
F010 5.4  
F004 5  
F005 ME  
F006 Undiluted API 84-01 was applied at doses of 200, 1000 and  
\*\* 2000 mg/kg/day to the shorn dorsal skin of groups of five  
\*\* male and five female rabbits. The test material was applied  
\*\* to the skin 3 times each week for 4 weeks (12 applications  
\*\* total  
F007 Undiluted API 84-01 was applied at doses of 200, 1000 and  
\*\* 2000 mg/kg/day to the shorn dorsal skin of groups of five  
\*\* male and five female rabbits. The test material was applied  
\*\* to the skin 3 times each week for 4 weeks (12 applications  
\*\* total). The applied material was covered with an occlusive

\*\* dressing for 6 hours, which was then removed and the skin  
 \*\* was  
 \*\* wiped with a dry gauze to remove any residual material. A  
 \*\* group of five rabbits of each sex served as sham controls.  
 \*\* The test skin site of each animal was examined and scored  
 \*\* for irritation prior to each application of test material.  
 \*\* Mortality and moribundity checks were performed twice daily  
 \*\* and body weights were recorded weekly. At termination,  
 \*\* blood samples were taken for a range of hematological and  
 \*\* clinical chemical measurements. Urine samples were also  
 \*\* collected and frozen for possible future examination. A  
 \*\* complete gross necropsy was performed on all animals. Major  
 \*\* organs were weighed and tissues were processed for  
 \*\* subsequent histopathological examination.

F008 IUC31

F020 3857

EOR

F002 40

F010 5.4

F004 5

F005 RE

F006 American Petroleum Institute (1986)

\*\* 28 day dermal toxicity study in the rabbit

\*\* API 84-01 Light paraffinic distillate CAS 64741-50-0

\*\* API Med. Res. Publ. 33-31642

F007 American Petroleum Institute (1986)

\*\* 28 day dermal toxicity study in the rabbit

\*\* API 84-01 Light paraffinic distillate CAS 64741-50-0

\*\* API Med. Res. Publ. 33-31642

F008 IUC4

F009 11-09-2010

F020 3858

EOR

F002 40

F010 5.4

F004 5

F005 RS

F006 Three animals died during the study but these were not

\*\* dose-related and were, therefore, considered unrelated to

\*\* treatment. Sporadic clinical signs were also unrelated to

\*\* treatment.

\*\* In the high dose group, body weight gains were affected b

F007 Three animals died during the study but these were not

\*\* dose-related and were, therefore, considered unrelated to

\*\* treatment. Sporadic clinical signs were also unrelated to

\*\* treatment.

\*\* In the high dose group, body weight gains were affected by

\*\* treatment. In the females, there was a group net loss in

\*\* weight whereas in the males the gains were significantly

\*\* less than controls. These effects were largely due to

\*\* effects on growth rate during the first week of the study.

\*\* A mean irritation index was calculated for each group each

\*\* day and also for each treatment group overall. The value

\*\* was determined from Draize scores for erythema and edema for

\*\* each animal. The mean irritation scores for each group

\*\* were:

** Group	Irritation	score
----------	------------	-------

```

** Control (male)          0
** Control (female)       0
** 200 mg/kg (male)       0.5
** 200 mg/kg (female)     0.4
** 1000 mg/kg (male)      1.7
** 1000 mg/kg (female)    2.0
** 2000 mg/kg (male)      3.1
** 2000 mg/kg (female)    3.2

```

There were no statistical differences between treated and control groups for any of the hematological determinations. These were: Total red blood cells, total white blood cells, hemoglobin concentration and hematocrit %.

The clinical chemical data for the treated and control males was similar. In the females, there was a reduced BUN and an increased SGPT for the low dose females. Since no other differences were noted and that values were within normal limits the effects were not considered to be toxicologically significant. The clinical chemical measurements consisted of: glucose, BUN, SGOT, SGPT, ALP and total protein.

The following absolute and relative organ weight differences (compared to controls) were recorded.

```

** 2000 mg/kg
**           Males          Females
** Relative liver wt. Increased  Increased
** Relative kidney wt.          Increased  Increased
** Relative pituitary wt.       Increased
** Relative left testis wt. Decreased
** Relative brain wt.           Increased
**
** 1000 mg/kg
**
** Abs. Rt. kidney   wt.   Decreased
** Abs. Heart wt.           Decreased

```

None of the organ weight differences were considered treatment-related. The higher than control relative organ weights were considered as a function of the reduced body weights in the affected animals.

The only findings at gross necropsy were confined to the treated skin. These consisted of dry, scaly, rough, and/or reddened skin and thickened dermis. These findings were noted throughout the treatment groups. There were no treatment-related gross necropsy findings in the internal organs.

Microscopic pathology findings were also largely confined to the skin. Slight to moderate proliferative changes of the skin were present in all of the male and female rabbits in the highest dose group.

The testes of one of the five males in the high dose group had bilateral diffuse tubular hypoplasia accompanied by

\*\* aspermatogenesis and hypoplasia of the epididymis. These  
 \*\* changes were considered to represent immature testes.  
 \*\* Similar changes were not seen in the other animals in this  
 \*\* dose group.  
 F008 IUC31  
 F020 3859  
 EOR  
 F002 40  
 F010 5.4  
 F004 7  
 F005 ME  
 F006 Groups of 10 male and 10 female rats were exposed to aerosol  
 \*\* concentrations of the three test materials at nominal  
 \*\* concentrations of 0, 50, 220 and 1000 mg/m3.  
 \*\* Exposures were for 6 hours each day, 5 days each week for 4  
 \*\* weeks. Total number  
 F007 Groups of 10 male and 10 female rats were exposed to aerosol  
 \*\* concentrations of the three test materials at nominal  
 \*\* concentrations of 0, 50, 220 and 1000 mg/m3.  
 \*\* Exposures were for 6 hours each day, 5 days each week for 4  
 \*\* weeks. Total number of exposures for each of the three test  
 \*\* materials was: 17, 18 and 20 days for SRO, WTO and HBO  
 \*\* respectively. Food and water were available ad libitum  
 \*\* during non-exposure periods.  
 \*\* Clinical observations were made prior to each exposure and  
 \*\* body weights were recorded weekly.  
 \*\* Animals were sacrificed within 72 hours of the last  
 \*\* exposure after being fasted overnight. Blood samples were  
 \*\* taken for a range of hematology and serum chemical  
 \*\* parameters. The hematological parameters consisted of: Total  
 \*\* white and red cells, hemoglobin, hematocrit, MCV, MCH, and  
 \*\* MCHC. A differential white cell count was also conducted.  
 \*\* The following chemical parameters were measured: Alanine  
 \*\* transferase, albumin, albumin/globulin ratio, alkaline  
 \*\* phosphatase, aspartate aminotransferase, total bilirubin,  
 \*\* calcium, chloride, cholesterol, creatinine, globulin,  
 \*\* glucose, iron, lactate dehydrogenase, inorganic phosphorus,  
 \*\* potassium, total protein, sodium, triglycerides, urea  
 \*\* nitrogen and uric acid.  
 \*\* All animals were necropsied and the following organs were  
 \*\* weighed: gonads, heart, kidneys, liver, spleen, and thymus.  
 \*\* The right middle lobe of the lung was weighed immediately  
 \*\* after removal and again after drying.  
 \*\* A range of tissues were fixed and prepared for a  
 \*\* histopathological examination.  
 \*\* Sperm from the cauda epididymis of each control and high  
 \*\* dose male was examined for an assessment of sperm  
 \*\* morphology.  
 F008 IUC31  
 F020 3860  
 EOR  
 F002 40  
 F010 5.4  
 F004 7  
 F005 RE  
 F006 Dalbey, W., Osimitz, T., Kommineni, C., Roy, T., Feuston,  
 \*\* M., and Yang, J. (1991)

\*\* Four-week inhalation exposures of rats to aerosols of three  
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F007 Dalbey, W., Osimitz, T., Kommineni, C., Roy, T., Feuston,  
\*\* M., and Yang, J. (1991)

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F008 IUC4

F009 11-09-2010

F020 3861

EOR

F002 40

F010 5.4

F004 7

F005 RL

F006 It is not clear whether the study was carried out according  
\*\* to GLP, but otherwise it was a well conducted and well  
\*\* reported study.

F007 It is not clear whether the study was carried out according  
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F008 IUC31

F020 3862

EOR

F002 40

F010 5.4

F004 7

F005 RS

F006 Chamber concentrations

\*\* The aerosol concentrations were comparable among the three  
\*\* base stocks.  
\*\* Qualitatively, the aerosols were virtually identical to each  
\*\* liquid base oil.  
\*\* The actual concentrations for each of the aerosols was as  
\*\* follows:

F007 Chamber concentrations

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\*\* base stocks.  
\*\* Qualitatively, the aerosols were virtually identical to each  
\*\* liquid base oil.  
\*\* The actual concentrations for each of the aerosols was as  
\*\* follows:

	Nominal	Actual
SRO	0	0
	50	50 ±10
	220	210 ±10
	1000	1020 ±60
WTO	0	0
	50	50 ±10
	220	210 ±10
	1000	980 ±20
HBO	0	0
	50	47 ±2
	220	220 ±10

\*\* 1000 980 ±50

\*\* The mass median diameter was well under 2µm for each base stock

#### \*\* Toxicity assessment

\*\* Apart from occasional loose stool there were no treatment related clinical observations and body weights were unaffected by exposure.

\*\* No treatment related effects were found in any of the hematological or clinical chemical parameters that were measured.

\*\* The percent sperm with aberrant morphology, including breakage, was unaffected by exposure to any of the three base oils.

\*\* There were no treatment-related observations at necropsy and, with the exception of the lungs, there were no significant changes in organ weights .

\*\* Wet and dry lung weights increased in a dose-related manner. The percentage increases in wet weight are shown in the following table.

\*\* For simplicity increases are shown to nearest whole numbers

\*\* % Increase in wet lung weight

\*\* Sex Dose SRO WTO HBO

\*\* Female (mg/m3)

50	3	8	2
210	4	23*	34*
1000	38*	64*	36*

\*\* Male

50	5	-	1
210	12*	1	6
1000	33*	31*	32*

\*\* \* denotes differences that are statistically significant (P<0.05) compared to controls.

\*\* The ratios of wet to dry lung weights were significantly increased for both sexes at the highest dose concentration for all three base oils.

\*\* Morphologically, treatment related changes were only observed in the lungs and tracheobronchial lymph nodes. Foamy macrophages with numerous vacuoles of varying size were present in the alveolar spaces of the lungs of many of the exposed animals. The histological changes are summarized in the following table.

\*\* No. of animals in each group with a given histopathological change

\*\* Tissue/change

	Dose group		
SRO	50	210	1000
Lung			
1-2 Foamy macrophages (FM)		20	20 20
3-6 FM	0	0	20

**	Thickened alveolar wall	0	0	0
**	FM in alveolar interstitium	0	0	0
**	Mild alveolar PMN infiltrate	0	5	20
**	Lymph nodes			
**	Anterior mediastinal			
**	Macrophage accumulation	NE	NE	9
**	Tracheobronchial			
**	FM accumulation	NE	NE	19
**	Macrophage accumulation	NE	NE	0
**	WTO			
**	Lung			
**	1-2 Foamy macrophages (FM)	20	20	20
**	3-6 FM	0	20	
**	Thickened alveolar wall	0	0	0
**	FM in alveolar interstitium	0	0	0
**	Mild alveolar PMN infiltrate	0	0	19
**	Lymph nodes			
**	Anterior mediastinal			
**	Macrophage accumulation	NE	NE	0
**	Tracheobronchial			
**	FM accumulation	NE	NE	0
**	Macrophage accumulation	NE	NE	19
**	HBO			
**	Lung			
**	1-2 Foamy macrophages (FM)	0	16	16
**	3-6 FM	0	16	
**	Thickened alveolar wall	0	0	16
**	FM in alveolar interstitium	0	0	16
**	Mild alveolar PMN infiltrate	0	0	0
**	Lymph nodes			
**	Anterior mediastinal			
**	Macrophage accumulation	NE	NE	2
**	Tracheobronchial			
**	FM accumulation	NE	NE	0
**	Macrophage accumulation	NE	NE	3

\*\* NE denotes Not Evaluated

\*\* Only 16 animals in the HBO high dose group were examined

F008 IUC31

F020 3863

EOR

F002 40

F010 5.4

F004 7

F005 TS

F006 Three materials were examined in this study. The properties

\*\* of the materials designated SRO, WTO and HBO are shown in

\*\* the following table.

\*\* SRO Solvent refined oil CAS # 64742-70-7

\*\* WTO White oil CAS # 8042-47-5. [Prepared by severely

\*\* hydr

F007 Three materials were examined in this study. The properties

\*\* of the materials designated SRO, WTO and HBO are shown in

\*\* the following table.

\*\* SRO Solvent refined oil CAS # 64742-70-7

\*\* WTO White oil CAS # 8042-47-5. [Prepared by severely  
\*\* hydrotreating a dewaxed feedstock and then acid washing  
\*\* with fuming sulfuric acid.]

\*\* HBO Hydrotreated base oil CAS #64742-54-7 [Severely  
\*\* hydrotreated heavy paraffinic oil produced by treatment  
\*\* of the vacuum distillate with hydrogen at high temperature  
\*\* and pressure (hydrotreating and hydrocracking)].

	SRO	WTO	HBO
Viscosity at 100 °F		106	85 161
Pour point (°F)		20	15 -5
API Gravity	32.8	34.6	33.6
Furfural (ppm)		1	0 <1
Nitrogen (ppm)		44	- 8
Sulfur (wt.%)		0.20	- <0.06
Composition (wt.%)			
Paraffins	36	60	29.7
Mononaphthenes		22.3	- 30.6
Polynaphthenes		22.3	- 37.3
Monoaromatics		12.8	0 0.6
Diaromatics	3.3	0	0.8
Polyaromatics		1.4	0 1.0
Unidentified aromatics		0.4	0 0
Aromatic sulfur types		1.1	0 0

F008 IUC31

F020 3864

EOR

F002 40

F010 5.4

F004 8

F005 ME

F006 Groups of 5 male and 5 female rats were exposed to oil mists

\*\* generated from two highly refined oils. Exposures were by

\*\* inhalation six hours each day for a total of 10 days

\*\* The two oils were examined in separate experiments.

\*\* The dose groups

F007 Groups of 5 male and 5 female rats were exposed to oil mists

\*\* generated from two highly refined oils. Exposures were by

\*\* inhalation six hours each day for a total of 10 days

\*\* The two oils were examined in separate experiments.

\*\* The dose groups were:

\*\*

Group	Mean actual concentration	Mass median particle size
-------	------------------------------	------------------------------

	(mg/m3)	(µm)
--	---------	------

Controls	Air only	N/A
----------	----------	-----

Oil 1	55	1.5
-------	----	-----

	507	1.9
--	-----	-----

	1507	2.2
--	------	-----

\*\*

Oil 2	Air only	N/A
-------	----------	-----

**	50	1.5
**	513	1.9
**	1480	2.2
**		

\*\* No further experimental details are provided.

F008 IUC31  
F020 3865  
EOR  
F002 40  
F010 5.4  
F004 8  
F005 RE  
F006 Skyberg, K., Skaug, V., Gylseth, B., Pedersen, J. R. and  
\*\* Iversen, O. H. (1990)  
\*\* Subacute inhalation toxicity of mineral oils, C15-C20  
\*\* alkylbenzenes, and polybutene in male rats.  
\*\* Environmental Research Vol. 53., pp 48-61  
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\*\* Environmental Research Vol. 53., pp 48-61  
F008 IUC31  
F020 3866  
EOR  
F002 40  
F010 5.4  
F004 8  
F005 RE  
F006 Whitman, F. T., Freeman, J. J., Infurna, R. N. and Phillips,  
\*\* R. D. (1989)  
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\*\* lubricating oil mists  
\*\* The toxicologist Vol. 9., p 143  
F007 Whitman, F. T., Freeman, J. J., Infurna, R. N. and Phillips,  
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\*\* Evaluation of the acute and subacute inhalation toxicity of  
\*\* lubricating oil mists  
\*\* The toxicologist Vol. 9., p 143  
F008 IUC31  
F020 3867  
EOR  
F002 40  
F010 5.4  
F004 8  
F005 RL  
F006 The information is taken from a poster presentation and a  
\*\* reliability score cannot be assigned.  
\*\* However, the data are supportive of the other study on  
\*\* inhalation of oil mist reported by Dalbey et al.  
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F008 IUC31  
F020 3868  
EOR

F002 40  
 F010 5.4  
 F004 8  
 F005 RM  
 F006 A further two week inhalation study in rats has been  
 \*\* reported for two mineral oil mists (Skyberg et al, 1990)  
 \*\* The results largely confirm those described by Whitman et  
 \*\* al. with respect to liver weight changes and histological  
 \*\* observations i  
 F007 A further two week inhalation study in rats has been  
 \*\* reported for two mineral oil mists (Skyberg et al, 1990)  
 \*\* The results largely confirm those described by Whitman et  
 \*\* al. with respect to liver weight changes and histological  
 \*\* observations in respiratory tissues.  
 F008 IUC31  
 F020 3869  
 EOR  
 F002 40  
 F010 5.4  
 F004 8  
 F005 RS  
 F006 Oil 1  
 \*\* All treated animals survived to study termination.  
 \*\* The fur of all animals was saturated with test material and  
 \*\* the amount of material present was clearly related to the  
 \*\* exposure concentration.  
 \*\* Alopecia and scabs subsequently formed in  
 F007 Oil 1  
 \*\* All treated animals survived to study termination.  
 \*\* The fur of all animals was saturated with test material and  
 \*\* the amount of material present was clearly related to the  
 \*\* exposure concentration.  
 \*\* Alopecia and scabs subsequently formed in the highest 2 dose  
 \*\* groups.  
 \*\* Animals in the highest dose group were relatively  
 \*\* unresponsive to auditory stimulation.  
 \*\* Decreased body weight associated with a decrease in food  
 \*\* consumption was recorded for the high dose animals.  
 \*\*  
 \*\* Biologically significant increases in relative lung and  
 \*\* liver weights were observed in he males and females in the  
 \*\* high dose group but only in the mid dose females.  
 \*\* An increase in white cell counts and the percentage of  
 \*\* neutrophils and a decrease in the percentage lymphocytes was  
 \*\* observed in the high dose groups only.  
 \*\* There were no treatment related histopathological changes in  
 \*\* the lowest 2 dose groups. Animals in the highest dose group  
 \*\* exhibited the same changes as those observed in the  
 \*\* nasoturbinates and lungs of animals exposed to oil 2 (See  
 \*\* below)  
 \*\*  
 \*\* Oil 2  
 \*\* Clinical observations were the same as for those animals  
 \*\* exposed to Oil 1, except that there was no scabbing and no  
 \*\* treatment related alterations in food consumption.  
 \*\* There was a biologically significant increase in absolute  
 \*\* and relative lung weights in males and females at the high

\*\* dose and in females only at the mid dose.  
 \*\* Apart from elevated liver alanine and aspartate transaminase  
 \*\* levels in the high dose females there were no other  
 \*\* treatment related effects.  
 \*\* Histological effects considered to be treatment related  
 \*\* consisted of an increase in the amount of perivascular and  
 \*\* peribronchial lymphoid proliferations and an increase in  
 \*\* mixed inflammatory cell infiltrations in the terminal  
 \*\* bronchioles and alveolar ducts of the highest two dose  
 \*\* groups. Increases in the appearance of focal hyperplasia and  
 \*\* squamous cell metaplasia of the anterior nasal mucosa  
 \*\* associated with inflammatory cell infiltration was observed  
 \*\* in the two highest dose groups. These changes were  
 \*\* indicative of mild irritation of the nasal mucosa.  
 \*\*  
 \*\* The NOELs for the two oils were >50 mg/m3  
 F008 IUC31  
 F020 3870  
 EOR  
 F002 40  
 F010 5.5  
 F004 1  
 F005 CL  
 F006 Base stocks with no or low concentrations of PACs have low  
 \*\* Mutagenicity indices. Also, those oils that were negative in  
 \*\* the modified Ames assay (MI < 1.0) were not carcinogenic in  
 \*\* mouse skin painting studies.  
 \*\*  
 \*\* Those oils which were positive  
 F007 Base stocks with no or low concentrations of PACs have low  
 \*\* Mutagenicity indices. Also, those oils that were negative in  
 \*\* the modified Ames assay (MI < 1.0) were not carcinogenic in  
 \*\* mouse skin painting studies.  
 \*\*  
 \*\* Those oils which were positive in the modified Ames assay  
 \*\* had significant levels of PACs and were carcinogenic.  
 F008 IUC31  
 F020 3871  
 EOR  
 F002 40  
 F010 5.5  
 F004 1  
 F005 ME  
 F006 The method differed from the standard pre- incubation Ames  
 \*\* assay in the following respects.  
 \*\*  
 \*\* A DMSO extract of the test materials was tested in the  
 \*\* assay.  
 \*\*  
 \*\* The S9 fraction was obtained from Aroclor-induced  
 \*\* hamsters.  
 \*\*  
 \*\* An eightfold conc  
 F007 The method differed from the standard pre- incubation Ames  
 \*\* assay in the following respects.  
 \*\*  
 \*\* A DMSO extract of the test materials was tested in the

\*\* assay.  
 \*\*  
 \*\* The S9 fraction was obtained from Araclor-induced  
 \*\* hamsters.  
 \*\*  
 \*\* An eightfold concentration of S-9 was used in the assays.  
 \*\*  
 \*\* Twofold concentration of cofactor NADP was used.  
 \*\*  
 \*\* The DMSO extracts were tested over a range of concentrations  
 \*\* that permitted the construction of a dose-response curve.  
 \*\*  
 \*\* A Mutagenicity Index was determined for each assay. This was  
 \*\* the tangent to the dose response curve at zero dose.  
 \*\*  
 \*\* An assay was judged to be positive if the Mutagenicity Index  
 \*\* was greater than 1.0  
 F008 IUC31  
 F020 3872  
 EOR  
 F002 40  
 F010 5.5  
 F004 1  
 F005 RE  
 F006 Blackburn, G. R., Deitch, R. A., Schreiner, C. A. and  
 \*\* Mackerer, C. R. (1986)  
 \*\* Predicting tumorigenicity of petroleum distillation  
 \*\* fractions using a modified Salmonella Mutagenicity assay.  
 \*\* Cell Biol. Toxicol. Vol. 2. pp 63-84  
 F007 Blackburn, G. R., Deitch, R. A., Schreiner, C. A. and  
 \*\* Mackerer, C. R. (1986)  
 \*\* Predicting tumorigenicity of petroleum distillation  
 \*\* fractions using a modified Salmonella Mutagenicity assay.  
 \*\* Cell Biol. Toxicol. Vol. 2. pp 63-84  
 F008 IUC31  
 F020 3873  
 EOR  
 F002 40  
 F010 5.5  
 F004 1  
 F005 RE  
 F006 Blackburn, G.R., Deitch, R.A., Schreiner, C.A., Mehlman, M.  
 \*\* A. and Mackerer, C.R. (1984)  
 \*\* Estimation of the dermal carcinogenic activity of petroleum  
 \*\* fractions using a modified Ames assay.  
 \*\* Cell Biol. and Toxicol. Vol 1, No 1, pp 67-80  
 F007 Blackburn, G.R., Deitch, R.A., Schreiner, C.A., Mehlman, M.  
 \*\* A. and Mackerer, C.R. (1984)  
 \*\* Estimation of the dermal carcinogenic activity of petroleum  
 \*\* fractions using a modified Ames assay.  
 \*\* Cell Biol. and Toxicol. Vol 1, No 1, pp 67-80  
 F008 IUC31  
 F020 3874  
 EOR  
 F002 40  
 F010 5.5  
 F004 1

F005 RE

F006 Roy, T.A., Johnson, S.W., Blackburn, G.R., and Mackerer, C.R. (1988)

\*\* Correlation of mutagenic and dermal carcinogenic activities of mineral oils with polycyclic aromatic compound content.

\*\* Fund. Appl. Toxicol. Vol 10, pp 466-476

F007 Roy, T.A., Johnson, S.W., Blackburn, G.R., and Mackerer, C.R. (1988)

\*\* Correlation of mutagenic and dermal carcinogenic activities of mineral oils with polycyclic aromatic compound content.

\*\* Fund. Appl. Toxicol. Vol 10, pp 466-476

F008 IUC31

F009 23-09-2001

F020 3875

EOR

F002 40

F010 5.5

F004 1

F005 RS

F006 Roy describes the mutagenicity results for a range of petroleum-derived materials, 28 of which were lubricating oil base stocks.

\*\* A Mutagenicity Index (MI) was determined for each test material and this was compared to the PAC content and to

F007 Roy describes the mutagenicity results for a range of petroleum-derived materials, 28 of which were lubricating oil base stocks.

\*\* A Mutagenicity Index (MI) was determined for each test material and this was compared to the PAC content and to a carcinogenicity index that had also been determined for each material.

\*\* The results were as follows.

\*\*

** Sample	MI*	%PAC**	%T***	%T/LP****
** 5	0.9	0.9	0	4.17
** 6	0	0.3	0	0
** 7	0.9	0.9	2	4.17
** 8	0	0.6	0	0
** 9	0	0.3	0	0
** 10	0	0.7	2	3.28
** 12	2.4	3.1	4	5.93
** 13	9.1	10	26	71
** 14	0	0.7	2	3.45
** 15	0	0.2	0	0
** 16	3.9	3.7	6	1.6
** 17	4	3.1	8	14.3
** 18	3.6	4.9	10	21.7
** 19	6.5	5.2	10	23.4
** 20	9.2	7.7	40	138
** 26	0	0.5	2	2
** 27	0	0.5	2	3.92
** 28	0	0.3	0	0
** 29	0	0.6	0	0
** 30	0	0.6	0	0
** 32	10	12	54	154
** 33	5.9	7.8	42	73.7

**	34	4.1	4.1	50	104
**	35	1.2	1.2	4	6.25
**	36	2.1	1.5	18	38.3
**	37	0	0.7	2	2.13
**	38	4.5	4.6	24	46.2
**	39	0	1.2	0	0

\*\* \* MI denotes Mutagenicity index.

\*\* \*\* %PAC is weight% of 3-7 ring PNAs in the oil.

\*\* \*\*\* %T is the percentage of mice with tumors in skin  
 \*\* carcinogenicity studies reported elsewhere.

\*\* \*\*\*\* %T/LP is the percentage of mice with tumors  
 \*\* multiplied by the reciprocal of the latency period. The  
 \*\* author describes this as a carcinogenic potency index.

F008 IUC31

F020 3876

EOR

F002 40

F010 5.5

F004 1

F005 TS

F006 The baseoils tested had PAC contents ranging from 0.2 to 12%. It is  
 \* generally recognized that those base oils with PAC contents less than 3%  
 \* are highly refined oils whereas those with greater values are considered  
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F007 The baseoils tested had PAC contents ranging from 0.2 to 12%. It is  
 \* generally recognized that those base oils with PAC contents less than 3%  
 \* are highly refined oils whereas those with greater values are considered  
 \* to be poorly refined. This distinction was recognized and used by the EU  
 \* in its classification of base oils. (Ref 70, 75)

F020 3877

EOR

F002 40

F010 5.5

F004 2

F005 ME

F006 The test substance (Canthus 1000, a deasphalted, dewaxed  
 \*\* residual oil) was diluted 1:5 in DMSO and then shaken,  
 \*\* centrifuged and separated into 2 fractions. Two assays were  
 \*\* conducted for the test substance: an initial assay and a  
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F007 The test substance (Canthus 1000, a deasphalted, dewaxed  
 \*\* residual oil) was diluted 1:5 in DMSO and then shaken,  
 \*\* centrifuged and separated into 2 fractions. Two assays were  
 \*\* conducted for the test substance: an initial assay and a  
 \*\* repeat assay. All plates were evaluated following  
 \*\* approximately two days of incubation. Test volumes of 5, 10,  
 \*\* 15, 20, 30, 40, 50 and 60 µl/plate were prepared by dilution  
 \*\* of the DMSO fraction in DMSO and dosed at a final volume of  
 \*\* 60 µl. The volumes were added to each plate with metabolic  
 \*\* activation (hamster S9) and tester strain TA98 following the  
 \*\* procedures outlined by Blackburn et al., (1986) and the  
 \*\* methods described in the American Society for Testing  
 \*\* Materials (ASTM) document, "The Standard Test Method for

\*\* Determining Carcinogenic Potential of Virgin Base Oils in  
\*\* Metalworking Fluids". The same test volumes were used in the  
\*\* repeat assay.  
\*\* A positive control and vehicle control were tested  
\*\* concurrently.

\*\* Linear regression analysis (ASTM: E 1687-95) was performed  
\*\* on the test substances which caused an increase in the mean  
\*\* number of revertant colonies when compared to the vehicle  
\*\* control. Only data from the linear portion of the dose  
\*\* response curve was used to generate the mutagenicity index  
\*\* (MI). If the increase in revertant colonies was not  
\*\* statistically significant or if there was no increase in the  
\*\* mean number of revertant colonies, then the MI value was  
\*\* considered to be 0 (revertants/ $\mu$ l DMSO extract).

\*\* Data from both the initial and repeat assays on the test  
\*\* material (Canthus 1000) were pooled to generate a single  
\*\* linear MI value. With this procedure, an MI value > 1.0  
\*\* (revertants/ $\mu$ l DMSO extract) is considered indicative of a  
\*\* potential dermal carcinogen in mice (Blackburn et al, 1996).  
\*\* Conversely, a test substance is considered unlikely to be  
\*\* carcinogenic in mouse skin when the MI value is < 1.0  
\*\* (revertants/ $\mu$ l DMSO extract).

F008 IUC31

F020 3878

EOR

F002 40

F010 5.5

F004 2

F005 RE

F006 American Society of Testing Materials (ASTM)

\*\* The standard test method for determining carcinogenic  
\*\* potential of virgin base oils in metalworking fluids  
\*\* E-1687-98, Conshohocken, PA

F007 American Society of Testing Materials (ASTM)

\*\* The standard test method for determining carcinogenic  
\*\* potential of virgin base oils in metalworking fluids  
\*\* E-1687-98, Conshohocken, PA

F008 IUC4

F009 11-09-2010

F020 3879

EOR

F002 40

F010 5.5

F004 2

F005 RE

F006 Blackburn, G. R., Deitch, R. A., Schreiner, C. A. and

\*\* Mackerer, C. R. (1986)

\*\* Predicting tumorigenicity of petroleum distillation  
\*\* fractions using a modified Salmonella Mutagenicity assay.  
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F008 IUC31  
F020 3880  
EOR  
F002 40  
F010 5.5  
F004 2  
F005 RE  
F006 Blackburn, G. R., Roy, T. A., Bleicher Jr., W. T., Reddy, M.  
\*\* V. and Mackerer, C. R. (1996)  
\*\* Comparisons of biological and chemical predictors of dermal  
\*\* carcinogenicity of petroleum oils  
\*\* J. Polycyclic aromatic compounds Vol 11 pp 201-210  
F007 Blackburn, G. R., Roy, T. A., Bleicher Jr., W. T., Reddy, M.  
\*\* V. and Mackerer, C. R. (1996)  
\*\* Comparisons of biological and chemical predictors of dermal  
\*\* carcinogenicity of petroleum oils  
\*\* J. Polycyclic aromatic compounds Vol 11 pp 201-210  
F008 IUC4  
F009 11-09-2010  
F020 3881  
EOR  
F002 40  
F010 5.5  
F004 2  
F005 RE  
F006 Exxonmobil Biomedical Sciences Inc.  
\*\* (00MRL 18)  
F007 Exxonmobil Biomedical Sciences Inc.  
\*\* (00MRL 18)  
F008 IUC31  
F020 3882  
EOR  
F002 40  
F010 5.5  
F004 2  
F005 RL  
F006 This summary is based on a summary of the results of a  
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\*\* It is not possible, therefore to assign a reliabilty to this  
\*\* study.  
\*\* The data however are useful, together with other similar  
\*\* data to demonstrate that residual base oils are not  
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\*\* data to demonstrate that residual base oils are not  
\*\* mutagenic in a modified Ames assay.  
F008 IUC31  
F020 3883  
EOR  
F002 40  
F010 5.5  
F004 2  
F005 RS

F006 The MI for Canthus 1000 was determined to be 0.2  
\*\* revertants/ $\mu$ l DMSO extract.  
\*\* Thus, under the conditions of this study, Canthus 1000 was  
\*\* considered negative for inducing frameshift mutations in  
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F008 IUC31  
F020 3884  
EOR  
F002 40  
F010 5.5  
F004 3  
F005 RE  
F006 EMBSI  
\*\* 01.MRL.66  
F007 EMBSI  
\*\* 01.MRL.66  
F008 IUC31  
F020 3885  
EOR  
F002 40  
F010 5.5  
F004 3  
F005 RE  
F006 Petrolabs (1998)  
\*\* H-Mobil-67763-Vacuum Resid.  
F007 Petrolabs (1998)  
\*\* H-Mobil-67763-Vacuum Resid.  
F008 IUC31  
F020 3886  
EOR  
F002 40  
F010 5.5  
F004 3  
F005 RE  
F006 Petrolabs (2000)  
\*\* H-Mobil-68351-Bright stock  
F007 Petrolabs (2000)  
\*\* H-Mobil-68351-Bright stock  
F008 IUC31  
F020 3887  
EOR  
F002 40  
F010 5.5  
F004 3  
F005 RL  
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\*\* study. It is not possible, therefore, to assign a

\*\* reliability to this study.  
 \*\* The data, however, are useful, together with other similar  
 \*\* data, to demonstrate that residual base oils are not  
 \*\* mutagenic in a modified Ames assay.  
 F008 IUC31  
 F020 3888  
 EOR  
 F002 40  
 F010 5.5  
 F004 3  
 F005 RM  
 F006 Summaries are available on Modified Ames assays that have  
 \*\* been carried out on 3 additional residual base oils and a  
 \*\* vacuum residuum.  
 \*\* The results and references to the studies are shown below.  
 \*\* Under the conditions of this study, the test mat  
 F007 Summaries are available on Modified Ames assays that have  
 \*\* been carried out on 3 additional residual base oils and a  
 \*\* vacuum residuum.  
 \*\* The results and references to the studies are shown below.  
 \*\* Under the conditions of this study, the test materials were  
 \*\* considered negative for inducing frameshift mutations in  
 \*\* Salmonella typhimurium.  
 \*\*  

Material	Mutagenicity Index (MI)	Reference
Vacuum residuum	0.8	Petrolabs (1998)
Bright stock	0.11	Petrolabs (2000)
150 SUS Bright stock	0	EMBSI
150 Solvent		
Bright stock	0	EMBSI

 F008 IUC31  
 F020 3889  
 EOR  
 F002 40  
 F010 5.6  
 F004 1  
 F005 ME  
 F006 A full description of the method is not given in the  
 \*\* publication.  
 \*\* The publication includes the following information:  
 \*\*  
 \*\* The rat bone marrow cytogenetics assay was performed after  
 \*\* administration of each sample of the test materials to 5-10  
 \*\* ma  
 F007 A full description of the method is not given in the  
 \*\* publication.  
 \*\* The publication includes the following information:  
 \*\*  
 \*\* The rat bone marrow cytogenetics assay was performed after  
 \*\* administration of each sample of the test materials to 5-10  
 \*\* males and 5-10 female Sprague Dawley rats per dose level.  
 \*\* In gavage studies, the samples were dissolved in corn oil or  
 \*\* saline and administered at a dosage of 5 ml/kg. Acute  
 \*\* studies and 5-day subchronic tests were performed in the  
 \*\* early stages of the work, but in subsequent assays only the

\*\* subchronic test was performed.  
 \*\* A positive control chemical, triethylenemelamine (TEM) was  
 \*\* tested concurrently.  
 F008 IUC31  
 F020 3890  
 EOR  
 F002 40  
 F010 5.6  
 F004 1  
 F005 RE  
 F006 Conaway, C. C., Schreiner, C. A. and Cragg, S. T. (1984)  
 \*\* Mutagenicity evaluation of petroleum hydrocarbons  
 \*\* In: Advances in modern experimental toxicology Volume VI:  
 \*\* Applied toxicology of hydrocarbons, pp 89-107.  
 \*\* Eds MacFarland et al., Prince  
 F007 Conaway, C. C., Schreiner, C. A. and Cragg, S. T. (1984)  
 \*\* Mutagenicity evaluation of petroleum hydrocarbons  
 \*\* In: Advances in modern experimental toxicology Volume VI:  
 \*\* Applied toxicology of hydrocarbons, pp 89-107.  
 \*\* Eds MacFarland et al., Princeton Scientific Publishers  
 F008 IUC31  
 F020 3891  
 EOR  
 F002 40  
 F010 5.6  
 F004 1  
 F005 RL  
 F006 The publication presents a summary of a program of work  
 \*\* carried out for the API.  
 \*\* Since raw data are not presented in the publication, a  
 \*\* reliability rating cannot be assigned.  
 \*\* Nevertheless, the information is useful in demonstrating the  
 \*\* lack  
 F007 The publication presents a summary of a program of work  
 \*\* carried out for the API.  
 \*\* Since raw data are not presented in the publication, a  
 \*\* reliability rating cannot be assigned.  
 \*\* Nevertheless, the information is useful in demonstrating the  
 \*\* lack of in-vivo genotoxic activity of the base oils  
 \*\* containing low levels of PACs.  
 F008 IUC31  
 F020 3892  
 EOR  
 F002 40  
 F010 5.6  
 F004 1  
 F005 RS  
 F006 The results tabulated in the publication are as follows:  
 \*\*  
 \*\* Sample Dose No. animals No. cells Aberrant  
 \*\* (mg/kg) cells (%)  
 \*\*  
 \*\* Paraffinic oils  
 \*\* 64 SUS Corn oil 8 400 4.3  
 \*\* 500 10 500 3.8  
 \*\* 1000 9 450 2  
 \*\* 2000 10 500 2.8

\*\* 133 SUS  
 \*\* Corn oil 1  
 F007 The results tabulated in the publication are as follows:

Sample (mg/kg)	Dose	No. animals	No. cells	Aberrant cells (%)
Paraffinic oils				
64 SUS Corn oil		8	400	4.3
500	10	500		3.8
1000	9	450		2
2000	10	500		2.8
133 SUS				
Corn oil	10	500		3
500	8	400		1.3
1000	10	500		2
2000	10	500		1
331 SUS				
Corn oil	10	500		4
500	9	450		3.8
1000	8	450		5.6
2000	10	500		7*
485 SUS				
Corn oil	7	350		4
500	9	450		4.9
1000	8	400		4.3
2000	7	350		5.7
990 SUS				
Corn oil	8	400		1
500	6	300		1.3
1000	9	450		1.6
2000	8	400		2.5
Naphthenic oils				
80 SUS Saline			19	950
500	17	850		0.4
1670	19	950		0.6
5000	20	1000		0.4
2000 SUS				
Saline			19	950
500	18	874		0.7
1670	18	900		1.6
5000	15	750		0.4
TEM				
0.4-1.0				24.2-41.8*

\*\* \* denotes significant by Wilcoxon rank test

F008 IUC31

F020 3893

EOR

F002 40

F010 5.6

F004 1

F005 TS

F006 Two naphthenic and 5 paraffinic base stocks were tested. The characteristics of the samples tested are as follows:

\*\*

Sample	Initial	Aromatics	PNAs
boiling	(%)	(%)	
point			
(° F)			

Paraffinic oils			
SUS at 100 °F			
64	536	10.2	0.4
133	63		

F007 Two naphthenic and 5 paraffinic base stocks were tested. The characteristics of the samples tested are as follows:

Sample	Initial	Aromatics	PNAs
boiling	(%)	(%)	
point			
(° F)			

Paraffinic oils			
SUS at 100 °F			
64	536	10.2	0.4
133	639	13.8	0.7
331	636	28.1	3.0
485	572	27.8	4.1
990	515	31.9	4.8

Naphthenic oils			
SUS at 100 °F			
80	470	23.8	0.8
2000	611	37.7	4.5

F008 IUC31

F020 3894

EOR

F002 40

F010 5.7

F004 2

F005 RE

F006 Bingham, E. Trosset, R. P., Warshawsky, D. (1980)

Carcinogenic potential of petroleum hydrocarbons, a critical review of the literature.

J. Environmental Pathology and Toxicology, Vol 3, pp 483-563.

F007 Bingham, E. Trosset, R. P., Warshawsky, D. (1980)

Carcinogenic potential of petroleum hydrocarbons, a critical review of the literature.

J. Environmental Pathology and Toxicology, Vol 3, pp 483-563.

F008 IUC31

F020 3895

EOR

F002 40

F010 5.7

F004 2

F005 RE

F006 Blackburn, G.R., Deitch, R.A., Schreiner, C.A., Mehlman, M. A. and Mackerer, C.R. (1984)

Estimation of the dermal carcinogenic activity of petroleum fractions using a modified Ames assay.

Cell Biol. and Toxicol. Vol 1, No 1, pp 67-80

F007 Blackburn, G.R., Deitch, R.A., Schreiner, C.A., Mehlman, M. A. and Mackerer, C.R. (1984)

\*\* Estimation of the dermal carcinogenic activity of petroleum  
 \*\* fractions using a modified Ames assay.  
 \*\* Cell Biol. and Toxicol. Vol 1, No 1, pp 67-80  
 F008 IUC31  
 F020 3896  
 EOR  
 F002 40  
 F010 5.7  
 F004 2  
 F005 RE  
 F006 CONCAWE (1994)  
 \*\* The use of the dimethyl sulphoxide (DMSO) extract by the IP  
 \*\* 346 method as an indicator of the carcinogenicity of  
 \*\* lubricant base oils and distillate aromatic extracts.  
 \*\* CONCAWE Report No. 94/51  
 \*\* CONCAWE, Brussels.  
 F007 CONCAWE (1994)  
 \*\* The use of the dimethyl sulphoxide (DMSO) extract by the IP  
 \*\* 346 method as an indicator of the carcinogenicity of  
 \*\* lubricant base oils and distillate aromatic extracts.  
 \*\* CONCAWE Report No. 94/51  
 \*\* CONCAWE, Brussels.  
 F008 IUC31  
 F020 3897  
 EOR  
 F002 40  
 F010 5.7  
 F004 2  
 F005 RE  
 F006 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F007 CONCAWE (1997)  
 \*\* Lubricating oil basestocks  
 \*\* Product dossier No. 97/108  
 \*\* CONCAWE, Brussels  
 F008 IUC31  
 F020 3898  
 EOR  
 F002 40  
 F010 5.7  
 F004 2  
 F005 RE  
 F006 IARC (1984)  
 \*\* IARC Monographs on the evaluation of the carcinogenic risk  
 \*\* of chemicals to humans, Volume 33: Polynuclear aromatic  
 \*\* hydrocarbons, part 2, carbon blacks, mineral oils (lubricant  
 \*\* base oils and derived products) and some nitroarenes  
 F007 IARC (1984)  
 \*\* IARC Monographs on the evaluation of the carcinogenic risk  
 \*\* of chemicals to humans, Volume 33: Polynuclear aromatic  
 \*\* hydrocarbons, part 2, carbon blacks, mineral oils (lubricant  
 \*\* base oils and derived products) and some nitroarenes.  
 \*\* International Agency for Research on Cancer, Lyon.  
 F008 IUC31  
 F020 3899

EOB

F002 40

F010 5.7

F004 2

F005 RE

F006 Roy, T.A., Johnson, S.W., Blackburn, G.R., and Mackerer,  
C.R. (1988)

Correlation of mutagenic and dermal carcinogenic activities  
of mineral oils with polycyclic aromatic compound content.  
Fund. Appl. Toxicol. Vol 10, pp 466-476

F007 Roy, T.A., Johnson, S.W., Blackburn, G.R., and Mackerer,  
C.R. (1988)

Correlation of mutagenic and dermal carcinogenic activities  
of mineral oils with polycyclic aromatic compound content.  
Fund. Appl. Toxicol. Vol 10, pp 466-476

F008 IUC31

F009 23-09-2001

F020 3900

EOB

F002 40

F010 5.7

F004 2

F005 RM

F006 Numerous skin carcinogenicity studies have been carried out  
on lubricating base oils derived from distillates. Data from  
these studies have been summarized and reviewed elsewhere.

No single study is summarized here but the general  
conclusion

F007 Numerous skin carcinogenicity studies have been carried out  
on lubricating base oils derived from distillates. Data from  
these studies have been summarized and reviewed elsewhere.

No single study is summarized here but the general  
conclusions that may be drawn from the numerous studies are:

Highly refined base oils are not skin carcinogens.

Poorly refined or unrefined base oils are skin  
carcinogens.

A good correlation exists between skin carcinogenic  
potential and level of DMSO extractables and polycyclic  
aromatic compounds present in the base oil.

The degree of carcinogenicity is dependent on the level of  
polycyclic aromatic compounds present in the base oil.

When applied repeatedly to the skin, carcinogenic base  
oils are associated only with skin tumors and not with an  
increase in systemic tumors.

There is a good correlation between skin carcinogenicity  
and Mutagenicity Index as determined in a modified Ames  
assay.

F008 IUC31

F020 3901

EOR  
F002 40  
F010 5.7  
F004 4  
F005 RE  
F006 ExxonMobil (2001)  
\*\* Combined chronic toxicity/carcinogenicity study of white oil  
\*\* in Fischer 344 rats. Test substance 70cSt White oil.  
\*\* Study performed for CONCAWE  
\*\* Project No. 105970  
\*\* Exxon Biomedical Sciences Inc. New Jersey July 11, 2001  
F007 ExxonMobil (2001)  
\*\* Combined chronic toxicity/carcinogenicity study of white oil  
\*\* in Fischer 344 rats. Test substance 70cSt White oil.  
\*\* Study performed for CONCAWE  
\*\* Project No. 105970  
\*\* Exxon Biomedical Sciences Inc. New Jersey July 11, 2001  
F008 IUC4  
F009 11-09-2010  
F020 3902  
EOR  
F002 40  
F010 5.7  
F004 4  
F005 RM  
F006 This study is a study that was conducted according to OECD  
\*\* guidelines. It is not described in full in this summary  
\*\* since it is not one of the SIDS base set requirements.  
F007 This study is a study that was conducted according to OECD  
\*\* guidelines. It is not described in full in this summary  
\*\* since it is not one of the SIDS base set requirements.  
F008 IUC31  
F020 3903  
EOR  
F002 40  
F010 5.7  
F004 4  
F005 RS  
F006 Survival was unaffected by exposure to the test material.  
\*\* There were no treatment related clinical signs, or any  
\*\* effects on body weight, food consumption, food conversion  
\*\* efficiency or ophthalmology. Furthermore, there was no  
\*\* treatment rela  
F007 Survival was unaffected by exposure to the test material.  
\*\* There were no treatment related clinical signs, or any  
\*\* effects on body weight, food consumption, food conversion  
\*\* efficiency or ophthalmology. Furthermore, there was no  
\*\* treatment related effects on the hematological, serum  
\*\* chemistry or urinalysis parameters that were measured.  
\*\* At gross necropsy, there were no treatment-related gross  
\*\* observations and there were no treatment-related neoplastic  
\*\* changes.  
F008 IUC31  
F020 3904  
EOR  
F002 40  
F010 5.7

F004 4  
 F005 TS  
 F006 The test material is a 70 cSt white oil with an average  
 \*\* molecular weight of 485.  
 F007 The test material is a 70 cSt white oil with an average  
 \*\* molecular weight of 485.  
 F008 IUC31  
 F020 3905  
 EOR  
 F002 40  
 F010 5.7  
 F004 5  
 F005 RE  
 F006 Shoda, T, Toyoda, K, Uneyama, C., Takada, K. and Takahashi,  
 \*\* M. (1997)  
 \*\* Lack of carcinogenicity of medium-viscosity liquid paraffin  
 \*\* given in the diet to F344 rats.  
 \*\* Food and Chemical Toxicology Vol. 35, pages 1181-1190  
 F007 Shoda, T, Toyoda, K, Uneyama, C., Takada, K. and Takahashi,  
 \*\* M. (1997)  
 \*\* Lack of carcinogenicity of medium-viscosity liquid paraffin  
 \*\* given in the diet to F344 rats.  
 \*\* Food and Chemical Toxicology Vol. 35, pages 1181-1190  
 F008 IUC31  
 F020 3906  
 EOR  
 F002 40  
 F010 5.7  
 F004 5  
 F005 RL  
 F006 Although the experimental details are not provided here, the  
 \*\* information is nevertheless useful in establishing the lack  
 \*\* of carcinogenicity by the oral route.  
 F007 Although the experimental details are not provided here, the  
 \*\* information is nevertheless useful in establishing the lack  
 \*\* of carcinogenicity by the oral route.  
 F008 IUC31  
 F020 3907  
 EOR  
 F002 40  
 F010 5.7  
 F004 5  
 F005 RS  
 F006 There were slight increases in body weights in both sexes of  
 \*\* the 5% group (5% for males and 2.7% for females) at week  
 \*\* 104. Food consumption was also increased in the 5% groups  
 \*\* (11% for males and 8% for females total increase at week  
 \*\* 104). H  
 F007 There were slight increases in body weights in both sexes of  
 \*\* the 5% group (5% for males and 2.7% for females) at week  
 \*\* 104. Food consumption was also increased in the 5% groups  
 \*\* (11% for males and 8% for females total increase at week  
 \*\* 104). However, no significant treatment-related differences  
 \*\* between the control and treated groups were observed for  
 \*\* clinical signs, mortality or hematological findings.  
 \*\* In the 5% group, absolute liver and kidney weights were  
 \*\* increased in males and absolute and relative submaxillary

\*\* gland weight were reduced in females. Absolute and relative  
 \*\* weights of heart and spleen were unaffected by treatment.  
 \*\* The percentage increases/decreases in the 5% group were:

Organ	Absolute	Relative
Female		
Submaxillary gland	3% decrease	1.7% decrease
Male		
Liver	8.4% increase	not different
Kidney (R)	14.9% increase	not different
Kidney (L)	9.9% increase	not different

\*\* In the 5% male group, the increased absolute organ weights  
 \*\* were attributed to the slight increases in body weights.

\*\* A variety of tumors developed in all groups, including the  
 \*\* control group. However, all the neoplastic lesions were  
 \*\* histologically similar to those known to occur spontaneously  
 \*\* in F344 rats, and no statistically significant increase in  
 \*\* the incidence of any tumor type was found for either sex in  
 \*\* the treated groups.

\*\* Granulomatous inflammation in the mesenteric lymph nodes,  
 \*\* considered to be a reaction to paraffin absorption, was  
 \*\* observed with similar incidence and severity in both sexes  
 \*\* of the 2.5 and 5% groups.

\*\* The authors concluded that under the present experimental  
 \*\* conditions, the high dose, about 2000-200,000 times higher  
 \*\* than the current temporary acceptable daily intake, did not  
 \*\* have any carcinogenic potential in F344 rats. Furthermore,  
 \*\* the granulomatous inflammation observed in the mesenteric  
 \*\* lymph nodes was not associated with any development of  
 \*\* neoplastic lesions.

F008 IUC31

F020 3908

EOR

F002 40

F010 5.7

F004 5

F005 TS

F006 The test material was composed of equal quantities of eight  
 \*\* different commercially available liquid paraffins (highly  
 \*\* refined white oils) obtained from eight member companies of  
 \*\* the Japan Liquid Paraffin Industry.

\*\* Each of the eight liquid p

F007 The test material was composed of equal quantities of eight  
 \*\* different commercially available liquid paraffins (highly  
 \*\* refined white oils) obtained from eight member companies of  
 \*\* the Japan Liquid Paraffin Industry.

\*\* Each of the eight liquid paraffins complied with the  
 \*\* requirements of the Japanese food additive and Japanese  
 \*\* Pharmacopoeia standards. 5 of the component material had  
 \*\* been derived from petroleum by acid treatment and the other

\*\* eight had been derived by hydrotreatment.  
 \*\* The physical properties of a sample of the composite test  
 \*\* material were determined by CONCAWE and were as follows:  
 \*\*  
 \*\* Viscosity at 40°C 0.871  
 \*\* Viscosity at 100 °C 8.68  
 \*\* Ratio of naphthenic/paraffinic hydrocarbon 35/65  
 \*\* Average molecular weight 475  
 \*\* Carbon No. at 5% boiling point 25  
 F008 IUC31  
 F020 3909  
 EOR  
 F002 40  
 F010 5.7  
 F004 6  
 F005 ME  
 F006 0.01 ml of undiluted test material was spread three times  
 \*\* weekly over the shorn dorsal skin of a group of 50 female CF  
 \*\* No.1 mice. A further two groups of 5 female mice underwent  
 \*\* similar treatment and were killed after 22 or 52 weeks.  
 \*\*  
 \*\* The  
 F007 0.01 ml of undiluted test material was spread three times  
 \*\* weekly over the shorn dorsal skin of a group of 50 female CF  
 \*\* No.1 mice. A further two groups of 5 female mice underwent  
 \*\* similar treatment and were killed after 22 or 52 weeks.  
 \*\*  
 \*\* The appearance and development (or regression) of  
 \*\* superficial tissue masses was recorded weekly throughout the  
 \*\* study, to enable calculation of the latency period of those  
 \*\* subsequently diagnosed as being tumors.  
 \*\*  
 \*\* A positive control group of 50 female mice was treated with  
 \*\* an oil (N1) that had been shown in previous studies to be a  
 \*\* skin carcinogen. The mice in the positive control group  
 \*\* received the oil once a week for 22 weeks and then once  
 \*\* every 14 days for a total of 78 weeks.  
 \*\* A group of 50 untreated female mice served as negative  
 \*\* controls.  
 F008 IUC31  
 F020 3910  
 EOR  
 F002 40  
 F010 5.7  
 F004 6  
 F005 RE  
 F006 King, D. J. (1991)  
 \*\* 1156, 1157 and 1158: 2-Year skin painting study.  
 \*\* Toxicology report 25-90-0275  
 \*\* BP Group Occupational Health Centre  
 F007 King, D. J. (1991)  
 \*\* 1156, 1157 and 1158: 2-Year skin painting study.  
 \*\* Toxicology report 25-90-0275  
 \*\* BP Group Occupational Health Centre  
 F008 IUC31  
 F020 3911  
 EOR

F002 40  
F010 5.7  
F004 6  
F005 RL

F006 This report is a summary report and as a consequence does  
\*\* not provide full experimental details, but does provide  
\*\* sufficient information for a conclusion to be made on the  
\*\* skin carcinogenic potential of a non-solvent refined  
\*\* residual paraff

F007 This report is a summary report and as a consequence does  
\*\* not provide full experimental details, but does provide  
\*\* sufficient information for a conclusion to be made on the  
\*\* skin carcinogenic potential of a non-solvent refined  
\*\* residual paraffinic base oil.

F008 IUC31  
F020 3912

EOR  
F002 40  
F010 5.7  
F004 6  
F005 RS

F006 Minimal evidence of skin irritation was visible following  
\*\* treatment with the test materials.  
\*\* No treatment-related effects were observed on clinical  
\*\* condition, body weight gain or mortality (NB survival rates  
\*\* for treated animals are not incl

F007 Minimal evidence of skin irritation was visible following  
\*\* treatment with the test materials.  
\*\* No treatment-related effects were observed on clinical  
\*\* condition, body weight gain or mortality (NB survival rates  
\*\* for treated animals are not included in the report).  
\*\* Changes recorded at post mortem were considered normal.  
\*\* Histopathological examination of the skin of the treated  
\*\* mice provided no evidence of skin irritation and no tumors  
\*\* of epidermal origin were observed.

\*\*  
\*\* No cutaneous tumors were recorded in the group of untreated  
\*\* control mice (52% of animals survived to termination after 2  
\*\* years)

\*\*  
\*\* The positive control group had skin reactions at the  
\*\* treatment site which included redness, scabbing, cracking  
\*\* and flaking; histopathological examination confirmed the  
\*\* presence of chronic inflammation (acanthosis,  
\*\* hyperkeratosis, ulcers, parakeratosis and scabs). In  
\*\* addition, skin reactions, principally at the margins of the  
\*\* treatment site were frequently recorded and were  
\*\* particularly seen during the first 22 weeks of treatment.  
\*\* These reactions typically included abrasions and ulceration.  
\*\* The severity of the lesions was such that many animals were  
\*\* killed on humane grounds; only 24% of animals survived to 78  
\*\* weeks.

\*\* Histopathological examination of the skin revealed that over  
\*\* 78 weeks, 23 mice in the positive control group had 56  
\*\* tumors of epidermal origin, of which 39 were benign  
\*\* (papillomas and keratoacanthomas) and 17 were malignant  
\*\* (squamous cell carcinomas and one single malignant basal

\*\* cell tumor). The mean latency period was 37 weeks.

F008 IUC31

F020 3913

EOR

F002 40

F010 5.7

F004 6

F005 TS

F006 The test substance was described as:

\*\* "A non-solvent refined, deasphalted, dewaxed residual  
\*\* paraffinic lubricant base oil"

\*\*

\*\* Characteristic Value

\*\* Kinematic viscosity

\*\* at 40 deg C 1024 cSt

\*\* at 60 deg C 266.6 cSt

\*\* at 100 deg C 42.52

F007 The test substance was described as:

\*\* "A non-solvent refined, deasphalted, dewaxed residual  
\*\* paraffinic lubricant base oil"

\*\*

\*\* Characteristic Value

\*\* Kinematic viscosity

\*\* at 40 deg C 1024 cSt

\*\* at 60 deg C 266.6 cSt

\*\* at 100 deg C 42.52 cSt

\*\* Density at 15 deg C 0.9280 kg/l

\*\* Pour point +3 deg C

\*\* Flash point (COC) 315 deg C

\*\* Refractive index 1.5142

\*\* Color (D1500) 8.0

\*\* Molecular weight (D2502) 660

\*\* Sulfur 1.7% wt

\*\* Aniline point 105.0 deg C

\*\* Volatiles 3 hrs at 13 deg C 0.10%

\*\* Neutralization value 0.02 mg KOH/g

\*\* Viscosity gravity constant (D2140) 0.846

\*\* Refractivity intercept 1.0598

\*\* Molecular type (D2007)

\*\* Saturates 46.3% wt

\*\* Aromatics 45.6% wt

\*\* Polars 8.0% wt

\*\* Carbon type (D2140)

\*\* CA 15%

\*\* CN 19%

\*\* CP 66%

\*\*

\*\* Total and individual PCA concentrations on completion of  
\*\* study

\*\* Individual PCA mg/kg

\*\* Fluoranthene 0.2

\*\* Pyrene 0.9

\*\* Benz (a) anthracene 0.3

\*\* Chrysene/triphenylene 2.5

\*\* Benzo (a) anthracene 1.0

\*\* Benzo (e) pyrene 1.6

\*\* Benzo (a) pyrene 0.1

**	Perylene	0.1
**	Dibenz (a,j)anthracene	<0.1
**	Dibenz (a,h)anthracene	<0.1
**	Indeno (1,2,3-cd)pyrene	<0.1
**	Benzo (ghi)perylene	<0.1
**	Total PCA content (BP3 method)	7.0% wt

F008 IUC31  
F020 3914  
EOR  
F002 40  
F010 5.7  
F004 7  
F005 ME  
F006 The summary states that the design of the study was similar  
\*\* to other conventional skin painting studies in mice.  
\*\*  
\*\* The test material was applied undiluted in 25 µl aliquots to  
\*\* the clipped dorsal back regions of 50 male C3H/HeJ mice,  
\*\* three ti  
F007 The summary states that the design of the study was similar  
\*\* to other conventional skin painting studies in mice.  
\*\*  
\*\* The test material was applied undiluted in 25 µl aliquots to  
\*\* the clipped dorsal back regions of 50 male C3H/HeJ mice,  
\*\* three times weekly. At each treatment period, the dorsal  
\*\* skin was examined for the presence of papillomas/carcinomas,  
\*\* and each animal was also examined daily for any clinical  
\*\* signs of ill health. Treatment continued for 24 months. A  
\*\* complete necropsy was conducted at the time of sacrifice. In  
\*\* this study, Primol 185, a medicinal grade white mineral oil  
\*\* was applied undiluted and served as the negative control.  
\*\* Heavy Clarified Oil (HCO) was applied as a 10% solution in  
\*\* Primol 185, and served as the positive control.

F008 IUC31  
F020 3915  
EOR  
F002 40  
F010 5.7  
F004 7  
F005 RE  
F006 Exxon  
\*\* REHD (MR.32DO.84)  
F007 Exxon  
\*\* REHD (MR.32DO.84)  
F008 IUC31  
F020 3916  
EOR  
F002 40  
F010 5.7  
F004 7  
F005 RL  
F006 The information given is based on a summary of the study and  
\*\* hence it is not possible to assign reliability to the study.  
\*\* Nevertheless, the data provide useful information on the  
\*\* carcinogenic potential of residual base oils.  
F007 The information given is based on a summary of the study and  
\*\* hence it is not possible to assign reliability to the study.

\*\* Nevertheless, the data provide useful information on the  
 \*\* carcinogenic potential of residual base oils.  
 F008 IUC31  
 F020 3917  
 EOR  
 F002 40  
 F010 5.7  
 F004 7  
 F005 RS  
 F006 None of the animals treated with the test material or the  
 \*\* negative control material developed skin tumors, or any  
 \*\* other tumors considered treatment-related, over the course  
 \*\* of the study. The positive control material, 10% HCO,  
 \*\* responded as  
 F007 None of the animals treated with the test material or the  
 \*\* negative control material developed skin tumors, or any  
 \*\* other tumors considered treatment-related, over the course  
 \*\* of the study. The positive control material, 10% HCO,  
 \*\* responded as anticipated, producing squamous cell carcinomas  
 \*\* in 47 of 50 treated animals.  
 F008 IUC31  
 F020 3918  
 EOR  
 F002 40  
 F010 5.8.1  
 F004 1  
 F005 ME  
 F006 The method used was as described in OECD guideline 421.  
 \*\*  
 \*\* The base oil was administered by gavage at a dose of 1.15  
 \*\* mg/kg (bw) to a group of 12 male and 12 female Sprague  
 \*\* Dawley  
 \*\* rats. Rats designated F0 animals were dosed for a  
 \*\* minimum of 14  
 F007 The method used was as described in OECD guideline 421.  
 \*\*  
 \*\* The base oil was administered by gavage at a dose of 1.15  
 \*\* mg/kg (bw) to a group of 12 male and 12 female Sprague  
 \*\* Dawley  
 \*\* rats. Rats designated F0 animals were dosed for a  
 \*\* minimum of 14 days prior to mating. Dosing was continued  
 \*\* after mating until a total dosing period of 30 days had  
 \*\* elapsed for males and until day 4 of lactation for females  
 \*\* (39 days).  
 \*\* The animals were observed twice daily for appearance,  
 \*\* behavior, morbidity and mortality. Males and females were  
 \*\* also observed during dosing and for one hour thereafter.  
 \*\* Male F0 body weights were recorded weekly. Female F0 body  
 \*\* weights were also recorded weekly until evidence of mating  
 \*\* was observed and then on gestation days 0, 7, 14 and 20 and  
 \*\* on lactation days 1 and 4. Food consumption was also  
 \*\* recorded for F0 both sexes.  
 \*\* Animals were paired on a 1:1 basis. Positive evidence of  
 \*\* mating was confirmed either by the presence of sperm in a  
 \*\* vaginal smear or a vaginal plug. The day when evidence of  
 \*\* mating was identified was termed Day 0 of gestation.  
 \*\*

\*\* The following Fertility indices were calculated:

\*\* Female mating index

\*\* Male mating index

\*\* Female fertility index

\*\* Male fertility index

\*\*

\*\* All females were allowed to deliver their young naturally and rear them to post-natal day 4. Females were observed twice daily during the period of expected parturition for initiation and completion of parturition and for signs of dystocia. After parturition, litters were sexed and examined for evidence of gross malformations, numbers of stillborn and live pups.

\*\* Litters were examined daily and each pup received a detailed physical examination on days 1 and 4 of lactation. Any abnormalities were recorded.

\*\* The live litter size and viability index were calculated.

\*\* All surviving pups were necropsied on post-natal day 4.

\*\* A complete gross examination was made on all animals at necropsy.

\*\* Selected organs of parental animals were weighed and a wide range of tissues was fixed for subsequent histopathological examination.

F008 IUC31

F020 3919

EOR

F002 40

F010 5.8.1

F004 1

F005 RE

F006 WIL Research Laboratories Inc. (1995)

\*\* An oral reproduction/developmental toxicity screening study of \*\*\*\* in finished oil in rats.

\*\* Laboratory Study No. WIL-187007

F007 WIL Research Laboratories Inc. (1995)

\*\* An oral reproduction/developmental toxicity screening study of \*\*\*\* in finished oil in rats.

\*\* Laboratory Study No. WIL-187007

F008 IUC31

F020 3920

EOR

F002 40

F010 5.8.1

F004 1

F005 RL

F006 The study was on an oil additive in base oil at two concentrations. The base oil alone was used as the control. Therefore, no control was available with which to compare the study control group. However, since all the recorded values were w

F007 The study was on an oil additive in base oil at two concentrations. The base oil alone was used as the control. Therefore, no control was available with which to compare the study control group. However, since all the recorded values were within normal limits, it could be concluded that the

\*\* base oil was without effect.  
F008 IUC31  
F020 3921  
EOR  
F002 40  
F010 5.8.1  
F004 1  
F005 RS  
F006 Only the results for the base oil control group are reported  
\*\* below.  
\*\*  
\*\* There were no clinical findings and growth rates and food  
\*\* consumption values were normal.  
\*\* Fertility indices and mating indices for males and females  
\*\* were both 100%.  
\*\* At nec  
F007 Only the results for the base oil control group are reported  
\*\* below.  
\*\*  
\*\* There were no clinical findings and growth rates and food  
\*\* consumption values were normal.  
\*\* Fertility indices and mating indices for males and females  
\*\* were both 100%.  
\*\* At necropsy, there were no consistent findings and the  
\*\* animals were considered to be normal.  
\*\* Organ weights and histopathology was considered normal.  
F008 IUC31  
F020 3922  
EOR  
F002 40  
F010 5.8.1  
F004 2  
F005 ME  
F006 72 female and 36 male Sprague-Dawley rats were given white  
\*\* oil at a dose of 5 ml/kg, 5 days a week for 13 weeks. After  
\*\* this time each of the males was housed with 2 females for 10  
\*\* consecutive nights, or until mating was confirmed by the  
\*\* ap  
F007 72 female and 36 male Sprague-Dawley rats were given white  
\*\* oil at a dose of 5 ml/kg, 5 days a week for 13 weeks. After  
\*\* this time each of the males was housed with 2 females for 10  
\*\* consecutive nights, or until mating was confirmed by the  
\*\* appearance of a copulatory plug or by the presence of sperm  
\*\* in a vaginal rinse.  
\*\* The mated females were maintained without further dosing  
\*\* through gestation and lactation to post-partum day 21.  
\*\* Detailed maternal physical examinations and body weight  
\*\* measurements were made on days 0, 7, 14 and 21 of gestation  
\*\* and on days 0, 4, 14 and 21 of lactation.  
\*\* All dams and surviving litters were sacrificed and grossly  
\*\* examined on day 21 of lactation. Each of the offspring was  
\*\* examined for external malformations. All pups were then  
\*\* sacrificed, necropsied and subjected to visceral organ and  
\*\* brain examination. Pups which died spontaneously were also  
\*\* necropsied unless this was precluded by cannibalism or  
\*\* aut  
F008 IUC31

F020 3923  
 EOR  
 F002 40  
 F010 5.8.1  
 F004 2  
 F005 RE  
 F006 McKee, R. H., Plutnick, R. T. and Traul, K. A. (1987)  
 \*\* Assessment of the potential reproductive and subchronic  
 \*\* toxicity of EDS coal liquids in Sprague-Dawley rats.  
 \*\* Toxicology Vol 46, pp 267-280  
 F007 McKee, R. H., Plutnick, R. T. and Traul, K. A. (1987)  
 \*\* Assessment of the potential reproductive and subchronic  
 \*\* toxicity of EDS coal liquids in Sprague-Dawley rats.  
 \*\* Toxicology Vol 46, pp 267-280  
 F008 IUC31  
 F020 3924  
 EOR  
 F002 40  
 F010 5.8.1  
 F004 2  
 F005 RL  
 F006 Not all the raw data are presented in this publication.  
 \*\* However, the data are useful in determining that white oils  
 \*\* do not cause effects on reproduction after prior exposure  
 \*\* for 13 weeks.  
 F007 Not all the raw data are presented in this publication.  
 \*\* However, the data are useful in determining that white oils  
 \*\* do not cause effects on reproduction after prior exposure  
 \*\* for 13 weeks.  
 F008 IUC31  
 F020 3925  
 EOR  
 F002 40  
 F010 5.8.1  
 F004 2  
 F005 RM  
 F006 White oil was used as solvent control in a study to  
 \*\* determine the effects of two EDS coal liquids in a 13 week  
 \*\* subchronic a single generation reproduction study.  
 \*\* There were three dose groups and a control  
 \*\* group for each test material in thi  
 F007 White oil was used as solvent control in a study to  
 \*\* determine the effects of two EDS coal liquids in a 13 week  
 \*\* subchronic a single generation reproduction study.  
 \*\* There were three dose groups and a control  
 \*\* group for each test material in this study.  
 \*\* The information in this robust summary relates only to the  
 \*\* white oil control groups (one for each of the test  
 \*\* materials) and NOT to the groups exposed to EDS coal  
 \*\* liquids.  
 \*\*  
 \*\* The CAS# for the material that was used in this study is not included in  
 \* the Lubricating Base Stocks category. However, because white oils are so  
 \* highly purified, toxicologically and compositionally they are all very  
 \* similar. Therefore, the Testing Group thinks the results on CAS #  
 \* 8012-95-1 are applicable to the highly refined base oils that are  
 \* included in this category.

F008 IUC31

F020 3926

EOR

F002 40

F010 5.8.1

F004 2

F005 RS

F006 The data for the two control groups are summarized below.

\*\*

Parameter	Control 1	Control 2
-----------	-----------	-----------

\*\*

Impregnation frequency	80.8%	80.9
------------------------	-------	------

\*\*

Gestation	22.6 days	22.6
Pups delivered	11.7	11.1
Live births	11.2	10.7
Survival at day 4	10.5	9.6
Surviva		

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Pups delivered	11.7	11.1
Live births	11.2	10.7
Survival at day 4	10.5	9.6
Survival at day 14	10.2	9.3
Survival at day 21	10.1	9.3

\*\*

Offspring body weights

Day 0 lactation	6.7	6.9
Day 4 lactation	9.3	9.9
Day 14 lactation	26.9	27.1
Day 21 lactation	43.2	46.7

\*\*

No unusual behavior was reported during the gestation period for either of the control groups.

The general condition of offspring and dams was good through weaning.

Gross observations of pups and dams were generally unremarkable.

In one base oil group, 3 malformed pups were found in 2 litters. Two of the malformed pups had syndactyly and renal agenesis and one of these also exhibited agnathia. The third pup had a small eye.

\*\*

In the other control group, four malformed pups were found in 4 litters. Two of the pups had tail abnormalities, one had a depression in the sternum and the fourth had a short snout.

\*\*

The authors comment that a similar spectrum of malformations in Sprague-Dawley rats from the same supplier has been

\*\* reported elsewhere. The authors also comment that this  
 \*\* spectrum of malformations can occur spontaneously in the  
 \*\* Sprague-Dawley rat and are not regarded as  
 \*\* treatment-related.  
 F008 IUC31  
 F020 3927  
 EOR  
 F002 40  
 F010 5.8.1  
 F004 2  
 F005 TS  
 F006 The test substance is not listed in the US HPV program.  
 \*\* Nevertheless, it is a white oil and the results are directly  
 \*\* applicable to other highly refined white oils.  
 F007 The test substance is not listed in the US HPV program.  
 \*\* Nevertheless, it is a white oil and the results are directly  
 \*\* applicable to other highly refined white oils.  
 F008 IUC31  
 F020 3928  
 EOR  
 F002 40  
 F010 5.8.2  
 F004 1  
 F005 ME  
 F006 Two groups of animals (50 and 25) were administered white oil  
 \*\* by gavage at a dose of 5 ml/kg, every day during gestation  
 \*\* days 6 to 19 inclusive. Food and water were available  
 \*\* continuously. Animals were examined for viability and  
 \*\* clinical e  
 F007 Two groups of animals (50 and 25) were administered white oil  
 \*\* by gavage at a dose of 5 ml/kg, every day during gestation  
 \*\* days 6 to 19 inclusive. Food and water were available  
 \*\* continuously. Animals were examined for viability and  
 \*\* clinical effects twice daily. Body weights were recorded on  
 \*\* days 0, 6, 10 and 20 of gestation.  
 \*\* On day 20 of gestation, all animals were euthanized with  
 \*\* methoxyfluorane and examined for gross changes. Each gravid  
 \*\* uterus was removed and weighed. The number, location and  
 \*\* viability of each fetus and the number of implant sites were  
 \*\* recorded. Fetuses were removed, weighed and the crown-rump  
 \*\* lengths measured. All live and dead fetuses that had not  
 \*\* been resorbed were examined for external malformations.  
 \*\* Approximately half of the fetuses from each litter were  
 \*\* decapitated and the heads preserved for subsequent  
 \*\* examination for abnormalities. The viscera were also  
 \*\* examined for malformations under low power magnification.  
 \*\* The remaining fetuses were stained with Alizarin red and  
 \*\* subsequently examined for skeletal abnormalities.  
 \*\* No organs, other than the uteri were weighed and no organs  
 \*\* were examined histologically in this study.  
 F008 IUC31  
 F020 3929  
 EOR  
 F002 40  
 F010 5.8.2  
 F004 1  
 F005 RE

F006 McKee, R. H., Pasternak, S. J. and Traul, K. A. (1987)  
 \*\* Developmental toxicity of EDS recycle solvent and fuel oil.  
 \*\* Toxicology Vol 46, pp 205-215  
 F007 McKee, R. H., Pasternak, S. J. and Traul, K. A. (1987)  
 \*\* Developmental toxicity of EDS recycle solvent and fuel oil.  
 \*\* Toxicology Vol 46, pp 205-215  
 F008 IUC31  
 F020 3930  
 EOR  
 F002 40  
 F010 5.8.2  
 F004 1  
 F005 RL  
 F006 Although there were no untreated animals for comparison, the  
 \*\* results were nevertheless, considered to be within normal  
 \*\* limits. Consequently, the study is useful in providing  
 \*\* evidence of the lack of developmental effects for white oil.  
 F007 Although there were no untreated animals for comparison, the  
 \*\* results were nevertheless, considered to be within normal  
 \*\* limits. Consequently, the study is useful in providing  
 \*\* evidence of the lack of developmental effects for white oil.  
 F008 IUC31  
 F020 3931  
 EOR  
 F002 40  
 F010 5.8.2  
 F004 1  
 F005 RM  
 F006 White oil was used as the solvent control in two separate  
 \*\* studies, one for each of two test materials.  
 \*\* This summary only reports on the outcome of the animals in  
 \*\* the two control groups.  
 \*\*  
 \*\* The CAS# for the material that was used in this stud  
 F007 White oil was used as the solvent control in two separate  
 \*\* studies, one for each of two test materials.  
 \*\* This summary only reports on the outcome of the animals in  
 \*\* the two control groups.  
 \*\*  
 \*\* The CAS# for the material that was used in this study is not included in  
 \* the Lubricating Base Stocks category. However, because white oils are so  
 \* highly purified, toxicologically and compositionally they are all very  
 \* similar. Therefore, the Testing Group thinks the results on CAS #  
 \* 8012-95-1 are applicable to the highly refined base oils that are  
 \* included in this category.  
 F008 IUC31  
 F020 3932  
 EOR  
 F002 40  
 F010 5.8.2  
 F004 1  
 F005 RS  
 F006 One animal died in the control group containing 50 animals  
 \*\* and this was attributable to misdosing.  
 \*\* Increases in body weight during the study were considered  
 \*\* normal. These with other recorded parameters are  
 \*\* summarized in the table below.

\*\*

\*\*

\*\* D

F007 One animal died in the control group containing 50 animals  
\*\* and this was attributable to misdosing.

\*\* Increases in body weight during the study were considered  
\*\* normal. These with other recorded parameters are  
\*\* summarized in the table below.

\*\*

\*\*

\*\* Day of gestation      Group 1      Group 2  
\*\*                              (25 rats)      (50 rats)

\*\*

\*\* Body weights (g)

\*\* 0                              207.2              225.4

\*\* 6                              227.5              248

\*\* 10                              235.9              259.3

\*\* 15                              260              284.3

\*\* 20                              329.1              351.9

\*\*

\*\* Uterine wt              67.2              70.7

\*\*

\*\* Number of litters      25              49

\*\* Implants/litter              11.3              12.0

\*\* Resorptions/litter      0.06              0.47

\*\*

\*\* Males

\*\* No./litter              5.12              5.96

\*\* Crown-rump length (mm)      3.66              3.6

\*\* Wt. of fetuses              4.26              4.23

\*\*

\*\* Females

\*\* No./litter              5.6              5.61

\*\* Crown-rump length (mm)      3.61              3.52

\*\* Wt. of fetuses              4.02              4.07

\*\*

\*\* In the control group containing 50 animals, 3 malformed  
\*\* fetuses were found in 3 litters; one had an extra lumbar  
\*\* vertebra, one had a discrete area of ossification in the  
\*\* area

\*\* of the junction of the frontal and nasal bones, one had  
\*\* moderately dilated lateral ventricles of the brain.

\*\*

\*\* 3 malformed fetuses were also found in 3 litters of the  
\*\* other control group. These were, a vertebral arterial canal  
\*\* of a cervical process fully ossified in 2 fetuses and  
\*\* angulated ribs in a third fetus.

\*\*

\*\* The authors considered these malformations to be minor and  
\*\* that the findings were within the normal ranges for the  
\*\* strain of rat.

F008 IUC31

F020 3933

EOB

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